ANIMAS CORP
Form 10-K
March 31, 2005

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

FORM 10-K

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

For the fiscal year ended December 31, 2004

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number 000-50674

ANIMAS CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**23-2860912**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
200 LAWRENCE DRIVE, WEST CHESTER, PA	**19380**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(610) 644-8990**

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

Title of Each Class	Name of each exchange on which registered
None	**N/A**

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.01 par value
(Title of class)

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 o.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes o No þ.

The aggregate market value of voting common stock held by non-affiliates of the registrant as of June 30, 2004 was: **$205,800,680**

The number of shares outstanding of the registrant s common stock as of March 24, 2005 was: **20,543,571**

DOCUMENTS INCORPORATED BY REFERENCE

Items 10,11,12,13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after close of the fiscal year covered by this annual report.

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PART I

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. When used in this report and the documents incorporated herein by reference, the words anticipate, believe, estimate, may, expect, intend, and similar expressions are generally to identify forward-looking statements.

These and other risks and uncertainties that could affect our actual results are discussed in this report and in our other filings with the Securities and Exchange Commission, particularly the section of this Form 10-K entitled Risk Factors. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements other than as required by applicable law.

We do not undertake any duty to update after the date of this report any of the forward-looking statements in this report to conform them to actual results.

Item 1. Business

Overview

We design, develop, manufacture, and sell external insulin pumps for people with diabetes. We were incorporated in Delaware in July 1996 and introduced our first generation pump in July 2000. We believe that we are the second largest supplier of pumps to the United States market in terms of new pump placements. We began shipping our third generation pump, the IR 1200, in April of 2004. We believe that the IR 1200 is the smallest full-featured insulin pump on the market. The IR 1200 has a large display, long battery life, precise insulin delivery, and enhanced waterproof integrity. In February of 2005, we began to ship the IR 1250. The IR 1250 utilizes the IR 1200 platform but includes additional software which incorporates a food database of up to 500 items and tunes for alerts. We also provide ancillary supplies on an ongoing basis for patients using our pumps, including insulin cartridges, infusion sets, batteries, and various accessories. We provide extensive education programs and services to people with diabetes.

From the introduction of the R1000, in July 2000, through December 31, 2004, we recorded over $95.5 million of revenue in pumps and $41.5 million of revenue in ancillary supplies. For the years ended December 31, 2004, 2003, and 2002, our net revenues were $67.9 million, $34.1 million, and $23.6 million, respectively.

We estimate that the size of the insulin pump and ancillary supplies market was over $540 million in the United States and over $780 million worldwide in 2004 and that the United States market has grown at a compound annual rate of over 20% during the past four years. We believe that approximately 250,000 people in the United States are using insulin pumps and that there is an estimated domestic market potential of over 1 million users. Given the increasing focus on intensive diabetes management and the opportunity to continue penetrating the potential user base, we believe that the insulin pump market is positioned for sustained growth.

We have approximately 125 full-time sales and clinical personnel located throughout the United States. Our approximate 55 person direct sales force promotes our pump in the United States to healthcare professionals who advise patients on monitoring and managing their diabetes and to patients who express interest in pump therapy. Our approximate 70 full-time equivalent diabetes educators, or clinical managers, train and provide clinical support to patients. We believe that our ratio of clinical to sales personnel is higher than our primary competitors, which we

believe helps us maintain a higher level of customer service and clinical support than our principal competitors. Our sales force and clinical managers also participate in many local community diabetes education programs and meetings and sponsor a number of courses both to educate the community in diabetes management generally and to increase awareness of pump therapy specifically.

We intend to introduce at frequent intervals innovative and new insulin pumps and related products enabling patients to better manage their diabetes and enjoy a better quality of life. These planned new products are intended to allow us to maintain our competitive position in the marketplace. They will generally supplant, in part or in whole, earlier product offerings. We are also developing a continuous glucose sensor.

Market Opportunity

Diabetes is a chronic, life-threatening disease for which there is no known cure. It is the sixth leading cause of death by disease in the

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United States. In the United States, diabetes was believed to cost over $132 billion in both direct and indirect costs in 2002. Only a small fraction of those costs represents medications, devices, and supplies to treat the disease. The vast majority of the costs are associated with complications of diabetes, stemming, in large part, from poor management of the disease.

Diabetes is a disease in which the body cannot adequately regulate blood glucose levels. Glucose supplies the body s tissue with energy. Glucose levels in the blood must be maintained within a specific concentration range to permit optimal cellular function and health. Insulin is a hormone, secreted by the pancreas, which regulates cellular metabolism of glucose. In people with diabetes, the body does not produce sufficient levels of insulin, or fails to utilize insulin effectively, which causes blood glucose levels to fall outside normal ranges. Failure to control blood glucose levels within normal ranges leads to severe complications over time, including blindness, kidney disease, nervous system disease, amputations, stroke, cardiovascular disease, and death.

More than 200 million people worldwide have diabetes. In the United States, there are more than 18 million people with diabetes, with about 13 million of these people diagnosed. The number of people in the United States diagnosed with diabetes has increased significantly in the last decade, primarily due to the aging of the population, inappropriate diet, and increasingly sedentary lifestyle. It is estimated that there are approximately 4 million patients with insulin-requiring diabetes in the United States.

Diabetes is typically classified as type 1 or type 2. Type 1 diabetes is characterized by near-complete absence of insulin secretion by the body. Although the onset of type 1 diabetes can occur at any age, it frequently is diagnosed during childhood or adolescence. Individuals with type 1 diabetes require daily insulin injections or insulin pump therapy to survive. We believe that there are 10 million people with type 1 diabetes worldwide, approximately 1.2 million of whom are in the United States.

Type 2 diabetes, the most common form of the disease, is characterized by insulin resistance (the body s inability to properly utilize insulin) and/or defects in insulin secretion (the body s inability to produce enough insulin). Initially, many patients with type 2 diabetes attempt to manage their diabetes by diet, exercise, and oral drugs. As their disease advances, they progress to multiple drug therapy, often including insulin. Many people with type 2 diabetes will eventually become insulin requiring, particularly as the insulin secretion defect advances. We estimate that there are more than 150 million people worldwide and about 17 million people in the United States with type 2 diabetes. Type 2 diabetes historically has occurred in later adulthood. However, largely due to inappropriate diet and sedentary lifestyle, type 2 diabetes is increasing in incidence among the younger population. Many healthcare professionals believe that this increase in the younger population will be a public healthcare problem of substantial magnitude in future years if this trend continues and if such afflicted patients are not aggressively treated.

Diabetes Therapy

Diabetes Management Challenges. Diabetes is frustrating and difficult to manage for patients, and can be significantly debilitating. Many of the debilitating effects stem from either hypoglycemia (low blood sugar levels) or hyperglycemia (high blood sugar levels). The blood sugars in people with diabetes tend to fluctuate from very high levels to very low levels over the course of a day. Blood sugar levels can be affected by 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. Excursions of high and low blood glucose levels can be frequent, unpredictable, and unsettling. 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 within normal ranges, a state that is nearly impossible to maintain without multiple daily injections or use of an insulin pump. Over-corrections are common and contribute to a roller coaster effect experienced routinely by many patients with diabetes. A range of factors can render diabetes overwhelming to patients and their families, including the time spent

in managing diabetes, the swings in blood sugar and their effects on the feeling of well being, and the fear of hypoglycemia. The rate of reported depression is significantly higher for people with diabetes than those without it.

Emergence of Intensive Management. Before the mid 1990s, conventional treatment for patients with type 1 diabetes consisted of administering one to two shots of insulin per day and eating meals of fixed carbohydrate loads at fixed times every day. Conventional treatment for patients with type 2 diabetes consisted of dietary management, exercise, and oral drugs, if necessary. Insulin was viewed as treatment of last resort for patients with type 2 diabetes and was typically prescribed only in the most advanced stages of the disease.

In the 1990s, two landmark trials demonstrated the importance of intensive therapy. First, in 1993, the Diabetes Control and Complications Trial (DCCT), conducted by the National Institutes of Health, demonstrated that complications of diabetes in people with type 1 diabetes could be delayed and the severity of complications reduced for those under intensive management of blood glucose levels or intensive therapy as opposed to conventional therapy. The intensive management regimen in the trial consisted of prescribed diet and/or exercise, three or more insulin injections per day or insulin pump therapy, frequent blood sugar measurements, and the adjustment of insulin and diet according to blood glucose levels.

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The regimen of patients under conventional management consisted of one to two insulin injections and one to two blood sugar tests per day. The trial showed that intensive therapy reduced the risk of complications in patients with type 1 diabetes by 76% for eye disease, 50% for kidney disease, and 60% for nerve disease. In 1998, a second trial, the United Kingdom Prospective Diabetes Study (UKPDS) Group, UK, demonstrated that intensive therapy significantly reduced the risk of these same microvascular complications associated with diabetes in patients with type 2 diabetes.

Today, the goal of intensive management is to achieve near-normal blood glucose levels without risking hypoglycemia. Many healthcare professionals believe that the more the insulin administration mimics a normal pancreas (more physiologic), the better the blood glucose control. We believe that many type 1 patients manage their diabetes intensively. A significantly smaller percentage of patients with type 2 diabetes practice intensive management. Recent guidelines, including those published by the American Diabetes Association, suggest aggressive treatment for patients with type 2 diabetes. It is now becoming more accepted that insulin should be taken earlier, even as first line therapy for some patients with type 2 diabetes.

Current Diabetes Management. There are four primary types of insulin therapy practiced today: conventional therapy; multiple daily injection (MDI) therapy using traditional insulins; MDI therapy using the newer (analog) insulins; and insulin pump therapy. Both the MDI therapies and the pump therapy are considered intensive management.

Patients with insulin-requiring diabetes need a continuous supply of insulin, known as basal insulin, to provide for background metabolic needs. In addition to basal insulin, such patients also require supplemental insulin, known as bolus insulin (also called mealtime or prandial insulin), to compensate for carbohydrates ingested or a high blood sugar level. Basal-bolus therapy is defined as patients receiving a basal or background infusion of insulin either via a pump or a long-acting insulin (such as Lantus) as well as receiving bolus insulin before meals or snacks.

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The following table shows the four primary methods of insulin therapy and selected advantages and disadvantages associated with each.

Type of therapy	Advantages	Disadvantages
Conventional therapy		
1 to 2 shots of insulin per day, typically a mixture of a long-acting and regular insulin, both of which exhibit insulin peaking	Easiest for healthcare professionals to teach Requires little cognitive ability on the part of the patient Lowest cost of supplies (insulin, syringes, etc.) of all therapies	Least physiologic approach Highest long-term complication rates Lowest quality of life Many hypoglycemic and hyperglycemic events roller coaster effect in blood glucose is common Variation in insulin absorption is common Limited lifestyle flexibility meals need to be timed to insulin peak
Intensive therapy: MDI with traditional insulins		
2 shots per day of a mixture of long-acting and regular insulin, both of which exhibit insulin peaking -plus - 1 to 2 shots of a rapid- acting insulin (before all meals and snacks)	Less complicated regimen than pump therapy Fewer long-term complications than with conventional therapy	Frequent shots (as many as 6 per day are not unusual) Many hypoglycemic and hyperglycemic events roller coaster effect in blood glucose is still common Variation in insulin absorption is common Limited lifestyle flexibility meals need to be timed to insulin peak
Intensive therapy: MDI with analog insulins		
1 to 2 shots per day of long-acting basal insulin (such as Lantus) -plus - 3 to 4 shots of insulin (before all meals and snacks)	Less complicated regimen than pump therapy Fewer long-term complications than conventional therapy Less hypoglycemia than with traditional insulins Can better accommodate changes to	Frequent shots (as many as six per day are not unusual) Roller coaster effect in blood glucose still occurs Lantus cannot be mixed with other insulins Dawn phenomenon (high blood

	timing/quantity of meals because of non-peaking insulins	sugars in early morning hours) cannot be corrected
Intensive therapy via insulin pump therapy		
No insulin injections-change infusion set every 3 rdays on average	Most physiologic approach Best control of blood glucose fewer long term complications Highest quality of life Enables most flexible lifestyle Insulin delivered discreetly and easily	Most complex approach of all insulin therapies to teach and learn Significant glucose monitoring required Highest upfront cost of all insulin therapies

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Benefits of Insulin Pump Therapy

Insulin pumps provide a number of key benefits:

Better Blood Glucose Control and Significant Improvement in Quality of Life. Pumps allow optimal tailoring of basal insulin release to meet the specific and varying basal needs of patients throughout the day. With injection therapy, there is no mechanism to adjust the basal insulin release. Pumps also provide greater consistency in basal insulin absorption due to the significantly smaller basal infusions and the use of rapid-acting as opposed to long-acting insulin. In addition, pumps allow patients to compensate for meals, correct high blood glucose levels, and control post-prandial blood glucose levels more optimally through use of boluses, either regular or extended. Extended boluses compensate for extended and delayed digestion, which can result from fatty meals or gastroparesis. Gastroparesis is a condition of delayed digestion found in over 20% of people with diabetes.

Increase Flexibility of Lifestyle. Pumps give patients flexibility with respect to eating and exercise. With injections, patients must eat whether they are hungry or not to compensate for peaking insulin, a falling blood sugar, or exercise. With pumps, patients may, in general, handle these same circumstances without being forced to eat by temporarily reducing their basal insulin.

Discreet, Easy, and Less Painful Insulin Administration. Pumps allow patients to administer insulin in an extremely discreet manner and with minimal pain. With injection therapy, patients need to pull out syringes and vials a minimum of twice a day and up to six to eight times per day. Because it is easier and less painful to bolus with a pump than with injections, patients on pumps tend to be more consistent about bolusing than those on injections.

As a result of these benefits, pump patients, in our experience, express a high level of satisfaction and enthusiasm about the therapy. Notably, healthcare professionals with diabetes have adopted pump therapy at a greater than 50% rate, far above the average rate in the population.

Barriers to Faster Insulin Pump Therapy Adoption

For Provider

Cost of a Pump-start. A pump-start typically requires between 8 and 20 hours of a provider s time between training the patient prior to initiation of pump therapy and following the patient after initiation. Third party reimbursement, for a pump-start averages below $250. Few providers can afford to underwrite the cost. Our competitors typically limit their role in the pump-start to providing training in pump operation, which accounts for less than 20% of the time involved in a pump-start.

Concern of Additional Non-reimbursed Work. Some providers worry that they will receive telephone calls, particularly after-hours calls, from patients on pumps. These come at a significant cost for providers, who typically are not reimbursed for telephone consultation.

Underestimation of Patients. Some providers have the misperception that only the most highly educated and motivated patients can manage intensive therapy, and, in particular, pump therapy.

Lack of Awareness. We estimate that over 75% of all diabetes is treated by primary care physicians (PCPs). PCPs typically receive little or no training in diabetes or insulin therapy during residency. A 2003 industry study showed that some PCPs are afraid of prescribing insulin (particularly mealtime insulin) and resist prescribing it to their type 2 patients for as long as possible. As such, PCPs have not historically

advocated intensive therapy.

For Patients

Lack of Awareness. Many patients still have not heard about intensive management or pump therapy. Even patients who have heard of intensive management or pump therapy often lack an understanding of the benefits of these therapies because they have not been properly educated.

Misconceptions. Some patients worry that being attached to a medical device represents a constant reminder of their

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disease and is intrusive to their daily lives. Other patients worry about their ability to manage the pump, and some others have body image issues associated with a pump.

Cost. Some patients cannot afford the co-pay associated with the purchase of a pump or the ongoing ancillary supplies or do not have medical insurance.

The Animas Solution

Our products enable people with diabetes to easily and accurately manage their blood glucose levels while maintaining a more flexible lifestyle. Through superior technology and service, we believe that we significantly address the major barriers to pump therapy.

Superior Technology. We believe that our newest product, the IR 1250, is the smallest full-featured pump on the market. The IR 1250 has a large display, long battery life, precise insulin delivery, and enhanced waterproof integrity.

The thin profile and small size of the IR 1250, with a footprint smaller than a business card, make the pump less intrusive.

The large screen and intuitive user interface make pump therapy less intimidating to patients and easier to teach and use.

The precise insulin delivery allows for optimal tailoring of basal insulin release to meet the specific and varying basal needs of patients throughout the day.

The sturdy construction, enhanced waterproof integrity, and long battery life make the pump compatible with patient lifestyles.

Excellent Service. We facilitate pump therapy for physicians and patients through our educational, clinical, and customer support. Our programs, including our Bridging the Gap program, provide patient education and clinical support customized to meet the needs of healthcare providers and patients.

For Providers

Bridging the Gap. Many providers do not have sufficient resources to conduct a pump-start. Our approximate 70 clinical managers, coupled with our network of per-diem certified diabetes educators, bridge the gap between the provider s resources and the resources necessary to do a pump- start.

Customer Support. Our 24/7 customer support function, staffed with healthcare professionals and others highly knowledgeable about pump therapy, relieves providers of costly telephone consultations and inconvenient after-hours calls.

Leadership in Education Programs. We sponsor a number of courses and seminars for healthcare professionals and those in training to increase their awareness of intensive management and pump therapy.

For Patients

Customer Support. Our knowledgeable staff is available to answer questions and provide solutions on a 24/7 basis.

Bridging the Gap. We seek to ensure patients success with pump therapy by proper training and follow-up for the first month of a pump-start.

Leadership in Education Programs. We sponsor a number of courses, seminars, and other community events for patients on a national, regional, and local basis to increase their awareness of intensive management and pump therapy.

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Convenient Reimbursement. Our Patient Administration group handles the reimbursement of a pump and ancillary supplies on behalf of patients. We also offer various programs for patients demonstrating financial need to help with out-of-pocket expenses.

Our Strategy

Our strategic objective is to be a leading provider of innovative insulin pumps and related products to allow better and easier management of diabetes. Through our superior technology and excellent service, we believe we can grow our customer base and increase our recurring net revenues from pumps and ancillary supplies. To achieve this objective, we are pursuing the following business strategies:

introduce at frequent intervals new and innovative insulin pumps and related products enabling patients to better manage their diabetes and enjoy a better quality of life;

expand the market for pump therapy and increase our market share by making pump therapy easier for both providers and patients;

capture sales of ancillary supplies through high patient retention;

increase international presence by expanding our network of local distributors and offering products with multilingual capabilities; and

enhance future profitability through gross margin improvement and organizational efficiency.

Our Products

Our external insulin pumps provide patients with an easy, comfortable, and flexible means of infusing insulin. Our pumps are pager-size devices which can be concealed in your clothes or on a belt. The pump delivers insulin through an infusion set, with a small, flexible cannula that is placed just beneath the skin. By delivering a rapid-acting insulin, the pump mimics the insulin delivery of a healthy, working pancreas for more predictable and tighter blood sugar control. For the years ended December 31, 2004, 2003, and 2002, our pump net revenues were $47.2 million, $21.2 million, and $17.8 million, respectively. Patients typically change their infusion sets and cartridge approximately every three days. These disposables provide us with a recurring source of net revenues following pump sales. For the years ended December 31, 2004, 2003, and 2002, our ancillary supplies net revenues were $20.7 million, $12.9 million, and $5.8 million, respectively.

IR 1250 Insulin Pump. The IR 1250 utilizes the IR 1200 platform, but has additional memory and software. All attributes ascribed to the IR 1200 below also apply to the IR 1250. We introduced the IR 1250 in February 2005 in the United States. Since launch of the IR 1250 in February, we are mostly selling the IR 1250 pump in the United States, but we are continuing to offer the IR 1000 and IR 1200 pumps outside the United States. The additional features of the IR 1250 over the IR 1200 are as follows:

Personalization Features. The IR 1250 stores personal information in the pump, including important contact information, allows patients to personalize basal program names for easy recognition and stores sick day tips from their healthcare team to help control their diabetes.

CarbSmart. With the IR 1250 and ezManager Plus, patients can upload the nutritional values of 500 food items from the CalorieKing® database which contains more than 5,000 foods and count the number of carbohydrates for up to nine food items for any one meal.

Program Pump Settings. The IR 1250 can be easily programmed through personal computers.

Customize Audio Notification. The IR 1250 allows patients to choose their own tunes or choose from popular music for most pump alert sounds.

IR 1200 Insulin Pump. The IR 1200 pumps (and its successor-generation pump, the IR 1250 pumps) weigh approximately 3.2 ounces and are the smallest full-featured pumps on the market. The IR 1200 is 25% smaller than its predecessor product, the IR 1000.

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We received FDA clearance for the IR 1200 in October 2003 and began shipping the IR 1200 in April 2004. We manufacture the IR 1200/1250 pumps, as well as the IR 1000, at our plant in West Chester, Pennsylvania. The IR 1200 has the following features:

Size and Aesthetics. The IR 1200 is small, thin, and sleek with various attractive metallic colors. Many patients, when otherwise not influenced by their healthcare provider, select a pump on the basis of aesthetics and size. Our pump s small size and thin profile make it more discreet and less intrusive whether worn inside clothing, on a belt, or in a pocket.

Precision Dosing. The IR 1200 allows basal insulin to be dosed in extremely small increments of one quarter of a microliter, which is half the size provided by our nearest competitor. Dosing this precise cannot be achieved using a syringe, insulin pen, or a competing pump. Precision dosing may be particularly beneficial to children, adolescents, and lean adults.

Superior User Interface. The IR 1200 has a large screen and our menu driven operation makes insulin dose-related calculations significantly easier. An intuitive user interface reduces the time it takes to teach patients how to use our pump, making pump therapy less intimidating to patients and secondary caregivers such as school nurses, grandparents, and others operating the pump.

Long Battery Life. The IR 1200 uses a AA lithium or alkaline battery, while the other full-featured pumps on the market use a AAA alkaline battery. Our battery typically provides approximately six to eight weeks of battery life, while the AAA alkaline provides from several days to 2 weeks under similar conditions.

Advanced Diagnostics and Safety Features. The IR 1200 detects a variety of conditions including occlusions (blockages) in the infusion set and malfunctions in the electronics, microprocessor, or mechanical systems. These features provide additional safety measures and increase patient confidence in using our pump.

Enhanced Waterproof Integrity. The IR 1200 has triple hermetically-sealed housings: one each for the battery, the cartridge, and the electronics. This triple hermetically-sealed housing design protects against pump damage even if the waterproof integrity is compromised through patient error. This can be particularly important for pediatric patients and active adults. Most of the pumps sold today are not waterproof.

R1000/ IR 1000 Pump. Our initial product, the R1000 insulin pump, received FDA clearance and was introduced to the market in 2000. Our second generation product, the IR 1000, received FDA clearance and was introduced to the market in 2002. The IR 1000 uses the same platform as the R1000, and provides infrared (IR) download of pump history and an improved user interface. We will continue to offer the IR 1000 internationally and to patients who are insulin-resistant and/or prefer the greater insulin capacity of the IR 1000 (300 units) versus the IR 1200 (200 units). We believe that the IR 1000 enjoys a reputation of being a durable, reliable pump with an excellent safety record.

Ancillary Supplies. Ancillary supplies represented a significant portion of our net revenues in 2004. We provide disposable cartridges and infusion sets to patients. Our cartridge for the IR 1000, the IR 1200, and the IR 1250 is proprietary to us and is made by a contract manufacturer. We currently obtain infusion sets from third parties. We also sell pump batteries and a variety of clothing supplies and other accessories.

ezManager/ezManager Plus. Our ezManager/ezManager Plus software package assists patients and their healthcare team with diabetes management. We received FDA clearance for the second generation ezManager Plus in June 2003. ezManager has two integrated software applications, one for PalmOS-based handhelds and one for desktop

(PC) computers. The PalmOS application allows users to quickly calculate their carbohydrate intake based on a list of consumed foods and record numerous logs relevant to their diabetes. It also makes corrective recommendations, based on the user s input.

GlucoWatch Biographer/AutoSensor. The GlucoWatch Biographer, a product developed by Cygnus, Inc, (Cygnus) and obtained by Animas in our asset purchase of Cygnus, in March 2005, is a non-invasive continuous glucose monitor, worn on the patient s wrist, which provides blood glucose readings every twenty minutes. It utilizes an electric field to extract sodium ions. Other small molecules, including glucose, contained in interstitial fluid are swept through the skin with the sodium ions. The GlucoWatch Biographer also contains a glucose-oxidase electrochemical sensor to measure the glucose extracted through the skin. The GlucoWatch Biographer has a disposable item, the AutoSensor that contains the electrodes used for extraction as well the electro-chemical sensor. The second -generation GlucoWatch (G2) Biographer has a two hour warm-up time upon inserting a new AutoSensor, at which time the patient typically calibrates the device using a fingerstick blood glucose reading, and a wear-time of 13 hours.

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Products Under Development

Next Generation Insulin Pumps. Our research and development team is working on several future generations of insulin pumps, including the IR 1275 and the IR 1500, in order to maintain a competitive advantage. We intend to introduce, at frequent intervals, new and innovative insulin pumps enabling patients to better manage their diabetes and enjoy a better quality of life. Our next generation insulin pumps are still in the development stage, requiring additional engineering and market development. Accordingly, we have not yet applied for FDA 510(k) clearance for any of our next generation pumps. Upon submitting 510(k) applications to the FDA and receiving 510(k) clearances from the FDA, we will be in the position to market the next generation pumps. We anticipate launching the IR 1275 either late in 2005 or early 2006 and the IR 1500 in the latter part of 2006.

ezSet Infusion System. We are developing our ezSet Infusion System, which will consist of the ezSet Infusion Set and the ezSet Inserter. The ezSet Infusion Set will provide greater comfort, security, ease of insertion, and flexibility than currently available infusion sets. The ezSet Inserter will be a small, lightweight, and stylish device that will provide quick and relatively painless catheter insertion. The ezSet Infusion System is in the development stage, requiring additional production and market development. We have received 510(k) clearances for earlier designs of our ezSet Infusion Set and Inserter. We anticipate the launch of the ezSet Infusion System in the middle part of 2005. We do not anticipate a significant conversion of existing patients (as of launch date) to this set and expect that the majority of our customers who use this set will be new customers.

Micro-Pump. In October 2004, we acquired an exclusive worldwide license to the micro-pump and micro-needle technology from Debiotech, SA (Debiotech) for the fields of insulin administration and glucose sensing. Benefits of the micro-pump technology include a significant reduction in device size, greater accuracy, faster occlusion detection, and greater precision. This technology also lends itself to marketability as a disposable pump. We have defined several possible product configurations and are in the process of determining the optimal configuration prior to initiating a detailed design project. We anticipate launch of our micro-pump based on the Debiotech technology in 2007.

Micro-Needles. The micro-needle offers the possibility of significantly less invasive means for infusing insulin and extracting interstitial fluid for blood glucose measurement. Our infusion set development efforts, in particular our MicroSet utilizes the micro-needle technology and holds promises for less pain, reduced inflammatory response, and better insulin absorption. At this time, we do not know when, if at all, our micro-needle technology will be commercially available.

Improved Cygnus Technology. The GlucoWatch Biographer suffers from several flaws that hamper market acceptance: excessive skips, excessive warm-up time, limited wear-time, susceptibility to interference by perspiration, skin irritation, excessive bulkiness, and inaccuracy. It has been postulated that most, if not all, of these drawbacks, can be significantly mitigated, with modifications to the device. Some of these modifications have been prototyped and limited testing indicates at least partial success in some of these areas of improvement. We are evaluating the commercial and technical feasibility of implementing such improvements, but have not yet formulated a plan for improvement, if any.

MicroWatch. The MicroWatch is a potential product combining the electrochemical sensor technology developed under Cygnus with the micro-needle technology licensed under the Debiotech agreement. Substituting the reverse electro-iontophoresis extraction with micro-needle technology offers the possibility of a future generation sensor with improved accuracy and less skin irritation. At this time, we do not know when, if at all, this technology will be commercially available.

Animas Long-term Implantable Continuous Glucose Sensor. Since our inception, we have been developing an implantable continuous glucose sensor. Our sensor is a long-term implantable device with no percutaneous (through the skin) wires. Measurements from the implantable sensor are transmitted by telemetry to an external display unit that can be worn on the patient s wrist or carried. Our sensor measures the near infrared spectra of venous blood at certain discrete wavelengths. By applying a universal algorithm to the measured spectra, blood glucose concentration can be determined. Although, we have had some promising preclinical results to date, there is a significant amount of development work remaining and we cannot accurately foresee when we will submit our pre-market approval (PMA) for this product and/or when this product may be commercially available.

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Sales, Clinical Support and Service

United States. We emphasize service and believe it has been in the past, and will continue to be so in the future, key to our success in this market. We currently have a national sales and support team of over 100 employees. Our sales force consists of approximately 55 sales representatives or territory managers. Our territory managers market primarily to endocrinologists, certified diabetes educators, and internal medicine physicians focused on diabetes. We primarily sell our products directly to patients through a referral by a healthcare provider or through a patient lead generated by one of our promotional activities. We also sell to durable medical equipment suppliers and distributors who, in turn, sell directly to the patient. For the years ended December 31, 2004, 2003, and 2002, our domestic net revenues were $63.0 million, $31.7 million, and $23.0 million, respectively. During the year ended December 31, 2004, approximately 14% of our domestic pump sales were sold through distributors.

In addition to our sales force, we have approximately 70 full-time equivalents clinical managers. Our clinical managers are all certified diabetes educators, with either a registered nursing or a registered dietician license. The primary responsibility of our clinical

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managers is to educate patients and provide clinical support to patients, as requested by the healthcare provider.

We have a several person sales force whose primary job function is to seek and maintain managed care contracts. We have over 400 contracts signed with third party payors, including most of the large national payors. On behalf of the patient, we obtain authorization and receive reimbursement by a patient s insurance provider(s) for our pump and disposable supplies with an internal staff of approximately 60 people. Even if we are not contracted with a particular payor, we can obtain authorization, in most instances, on a single-case negotiation basis. In some instances, when we are not a contracted provider, we may refer a pump order (subject to approval by the patient) to a distributor who is a contracted provider. It is important from a patient satisfaction perspective that we handle the reimbursement process efficiently and promptly. Healthcare providers demand that pump suppliers obtain authorization promptly and efficiently for their patients, This insurance process can be labor-intensive and complex.

To our knowledge, only one of our competitors has similar standing with third-party payors and has a similar infrastructure in house to efficiently process such orders. We believe that having both the infrastructure and contract capability provides us a competitive advantage over those competitors without such infrastructure or contract capability as it increases the likelihood of a pump being approved rapidly and with minimal disturbance to the healthcare provider. Our proprietary information technology system helps us perform these tasks efficiently.

Our sales of ancillary supplies, primarily infusion sets, cartridges, and batteries, are handled over the telephone. We call or send messages to patients to remind them to reorder their ancillary supplies. Our customer service focus, as well as our supply reminder program, drives our high patient retention rate. A patient, on the average, buys $1,300 per year of ancillary supplies and replaces his or her pump every three to five years.

Our marketing programs create awareness of our business and educate healthcare professionals and people with diabetes on the benefits of intensive therapy, methods of achieving better glucose control, and various aspects of pump therapy. To further generate awareness and penetrate the market, our sales, marketing, and clinical organization provide a wide range of education programs, support materials, and events at the national, regional, and local levels. These programs include public relations efforts, product training, conference and trade show attendance, seminars sponsored by us or others, educational courses, and educational and promotional literature.

We are fully committed to ensuring that each patient receives sufficient education and clinical support to enjoy the maximum benefits of pump therapy. To successfully start on a pump, a patient must master pump operation, diabetes management skills, and carbohydrate-counting skills. In addition, a healthcare professional must set and fine-tune the insulin dosing, a process that typically spans about four weeks. The total time required for a pump-start averages between training and dosing runs from 8 to 20 hours. Third party reimbursement for a pump-start covers only a small fraction of the true cost. Furthermore, many providers, including large teaching hospitals, do not have the resources to provide the clinical support to manage a pump-start. Our Bridging the Gap program provides custom patient education and clinical support, which complements the provider s efforts to successfully train and manage each patient. Historically, the norm within the pump industry has been only to provide pump-operation training.

We believe that we are in a unique position in the industry in our ability to provide a Bridging the Gap-type program due to the existence and structure of clinical manager organization. While our competitors also employ clinical managers, we believe that we employ more clinical managers than our closest principal competitor, in relation to the number of territory managers (sales representatives). In addition, in contrast to our competitors, our clinical managers do not have sales responsibilities and do not report into our sales organization.

Upon completion of the operational training on our pump, our clinical managers follow up with each patient to ensure that the patient is comfortable with pump therapy. Follow-up occurs regularly during the first few months of being placed on our pump and quarterly thereafter to make sure the patient is doing well. To our knowledge, our competitors

do not have any similar program and this program provides us a significant competitive advantage. We also believe we are unique in the industry in our ability to provide exceptional service on a 24/7 basis because of the structure of our clinical manager organization, coupled with our pump support group, that responds to patients questions. By ensuring that each patient is fully trained on pump operation and properly followed, we believe that we reduce the number of calls into our help-line. Furthermore, because we are staffed primarily with clinical personnel, highly knowledgeable about pump therapy, we can provide a better level of service than our competitors.

We believe that our focus on patient education and customer service has been a very important element in allowing us to both gain

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market share and grow the market.

International. We sell our products internationally through distributors focused primarily on the diabetes market. These distributors have established relationships with healthcare professionals and developed distribution channels. Under the terms of our arrangements with our distributors, they have responsibility for sales, marketing, and customer service in their respective territories. We may terminate the arrangement if, among other reasons, specified minimum purchase requirements for their respective territories are not reached. The arrangements generally contain terms from one to three years and contain automatic extension provisions. In certain select countries, we are negotiating or have already negotiated the right, but not the obligation, to buy our distributors business at some time in the future.

We obtained regulatory approval to market our R1000, IR 1000 and the IR 1200 in Canada in March 2001, July 2002 and September 2004, respectively. In June 2004, we upgraded our certification, under the Medical Device Directive, to ISO 9001-2000 and ISO 13485-2000, through BSI, Management Systems. This allows us to continue to CE mark and commercially distribute our products throughout the European Union. CE is an abbreviation for Conformite Europeene or European Compliance. Subsequent to affixing the CE mark, we need to obtain, in many countries, an additional approval in order to have the pump reimbursed by the government-paid insurance programs.

We are presently selling our pump products through distributors in Australia, Austria, Canada, the Czech Republic, France, Finland, Greece, Germany, Hungary, the Republic of Ireland, Israel, Italy, New Zealand, Spain, Sweden and the United Kingdom. For the years ended December 31, 2004, 2003, and 2002, our foreign net revenues were $4.9 million, $2.4 million, and $592,000, respectively.

We believe that our pump s multilingual capability and easy to use interface provide us with a significant competitive advantage, particularly in the international marketplace.

Medical Advisory Board

We have established a medical advisory board, consisting of individuals with recognized expertise in fields relating to diabetes treatment. Our members advise us concerning long-term product planning, research and development, and marketing. Members of our medical advisory board meet formally and informally with us. Our medical advisory board meets once or twice per year and each member s time commitment per year is eight hours. Each member is required to attend medical advisory board meetings and to be available to answer questions. Each member received a grant of 1,333 options to purchase our common stock at the beginning of his or her two year term. Several members of our medical advisory board are employed by academic institutions and may have commitments to, or agreements with, other entities that may limit their availability to us. Members of our medical advisory board may also serve as consultants to other medical product companies.

Information Technology

Our ACcessIT System is a company-wide database. Designed on client-server architecture, this application tracks all sales contacts, including clinicians information, actual and potential patient information, insurance verification, and order data processing. Two modules of ACcessIT allow us to store all the contractual data and billing information in one integrated system that facilitates the collection process. The same system handles our customer service and quality assurance needs such as call tracking, complaint registration, and returned goods authorizations. ACcessIT gives employees quick and accurate information that empowers them to do their job more efficiently and in much less time than with comparable systems.

Manufacturing and Quality Assurance

Our manufacturing facility is currently located in our headquarters in West Chester, Pennsylvania. We have approximately 105 employees in production, material control, manufacturing, quality, engineering, and shipping and receiving.

Our pump is assembled and tested in our West Chester facility. We purchase most of our components, some subassemblies, and various services used in the manufacture of our insulin pumps from outside vendors. These outside vendors generally produce their items to our specifications and in many instances to our designs. A contract manufacturer located outside the United States manufactures our insulin cartridge. We purchase our infusion sets from original equipment manufacturer suppliers.

Our Quality Assurance Department audits our vendors for conformance to our specifications, policies, and procedures and inspects and tests our products at various steps in the manufacturing cycle. This process facilitates compliance with the stringent specifications for our products.

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We rely on single sources for some important parts, including hybrid circuits, integrated circuits, and various products and components. We also have a sole source subcontract arrangement for sterilization services. We have never experienced disruption of such services and we have contingency plans in place. For example, we have established secondary source suppliers in certain circumstances and we create safety stocks to address changes in market demand. Arrangements for additional or replacement suppliers for some of these parts cannot be accomplished quickly and our business could be harmed by such delays.

Certain processes, as required by the FDA and other regulatory bodies, utilized in the manufacture and test of our products have been verified and validated. As a medical device manufacturer, our manufacturing facility and the facilities of our cartridge manufacturer and sterilizer are subject to periodic inspection by the FDA and certain corresponding state and international agencies.

Intellectual Property

We rely on a combination of copyright, patent, trademark, trade secret, and other intellectual property laws, nondisclosure agreements, and other measures to protect our proprietary rights. As of December 31, 2004, we had obtained 6 issued United States patents, and had 4 additional United States patent applications pending. We believe it will take up to five years, and possibly longer, for these United States patent applications to result in issued patents. Our issued patents expire between July 2016 and July 2020. The issued and allowed patents cover, among other things:

- the operation, components, design, and subsystems of our insulin pump;
- some novel aspects of our cartridge;
- some novel aspects of our infusion set;
- some novel aspects to our ezManager software; and
- the operation, components, design, and subsystems of our implantable glucose sensor.

In addition, we have obtained 2 foreign patents and have filed 12 foreign patent applications in 5 foreign patent offices seeking rights corresponding to aspects of our issued United States patents and pending United States patent applications.

We obtained exclusive worldwide license rights for diabetes from Debiotech of Lausanne, Switzerland. These license rights relate to 13 distinct United States patents specific to MEMS (Micro Electro-Mechanical Systems) pump technologies. The agreement with Debiotech also includes the licensing of future Debiotech patents related to the same technologies. The 13 United States patents licensed have expiration dates between April 2010 and August 2018. These patents also benefit from patent protection in numerous European countries, Canada and Japan. With the Debiotech licensing agreement, we also obtained worldwide license rights to a particular micro-needle technology which is currently filed as both a United States patent application and a PCT (Patent Cooperation Treaty) application.

With the Cygnus acquisition, we acquired 37 distinct United States patents all related to continuous glucose monitoring. These 37 patents have expiration dates between April 2018 and November 2024. We also acquired the rights to 22 United States patent applications and the rights of transfer from Cygnus to Animas the license of 5 United States patents assigned to the regents of the University of California. These 5 United States patents are specific to continuous glucose monitoring and they have expiration dates between January 2011 and March 2024. The 42 patents referenced in this paragraph also benefit from patent protection in numerous European countries, Canada and Japan.

As of December 31, 2004, we had registered the trademarks ANIMAS and EZ MANAGER with the United States Patent and Trademark Office on the Principal Register. We are in the process of filing a Community Trademark application for ANIMAS mark in the European Union countries, as well as filing a customs recordation of the EZ MANAGER mark.

We have applied with the United States Patent and Trademark Office to register the trademark EZ SET and have submitted a request for an extension of time to file a statement of use. On February 15, 2004, we submitted trademark applications to the United States Patent and Trademark Office to register the marks Micro-Pump, MicroSet, and MicroWatch. With the Cygnus acquisition, we acquired approximately 16 marks which have been registered in the United States Patent and Trademark Office, as well as in various countries.

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Research and Development

Our research and development efforts focus on developing future generation pumps, infusion sets, and continuous glucose sensing. Our research and development staff consists of approximately 35 people, including 2 who hold Ph.D. degrees. Our research and development staff has extensive experience in the medical device industry, including insulin pumps, infusion sets, surgical lasers, optoelectronics in medical applications, biosensors, hearing aids, pacemakers, and implantable defibrillators. We expect research and development expenses to continue to increase as we seek to enhance our existing product portfolio and develop additional products. We incurred research and development expenses of $20.8 million in 2004 (including the write-off of purchased in-process research and development of $14.5 million), $5.2 million in 2003 and $3.9 million in 2002.

Competition

The medical device industry is subject to intense competition. We have five principal competitors:

Medtronic MiniMed, a division of Medtronic Inc.;

Roche Disetronic, a division of Roche Diagnostics;

Smiths Medical MD, Inc. (formerly known as Deltec, Inc.), a subsidiary of Smiths Group plc;

Nipro Medical Corporation, a subsidiary of Nipro Corporation; and

Sooil Development Co., Ltd.

Some of our competitors are large, well capitalized companies with significantly greater resources for product development and marketing. Medtronic MiniMed (Medtronic) has the leading market share of the insulin pump market in the United States. Roche Disetronic has the leading market share of the insulin pump market in Europe. Roche Disetronic is currently prohibited by the FDA from selling its infusion pumps in the United States. We anticipate that Roche Disetronic will reenter the United States market in the second quarter of 2005.

Continuous monitoring or sensing is a very competitive field. We believe our acquisition of certain Cygnus assets has strengthened our intellectual property portfolio in continuous glucose sensing and has also provided us with a strong core-technology in electrochemical sensors.

To date, the FDA has approved, for adjunctive use only, two companies continuous glucose monitors or sensors, those developed by Cygnus and now owned by Animas, and those developed and owned by Medtronic. Unlike the current finger-stick blood glucose meters, devices labeled for adjunctive use should not be used for non-therapeutic use. We believe that this labeling is a significant limitation for wide-spread clinical use and wide-spread reimbursement.

The GlucoWatch Biographer, formerly owned by Cygnus and now owned by Animas (see Products Under Development for a complete description) is a non-invasive continuous glucose meter worn on the patient s wrist. It provides continuous blood glucose readings, for adjunctive use only; provides readings of blood glucose, updated every 20 minutes of blood glucose; and in addition contains both a hyperglycemic and hypoglycemic alarm. The GlucoWatch Biographer is the only device currently approved by the FDA and sold in the US market that provides real-time blood glucose readings. The second-generation GlucoWatch (G2) Biographer can be worn for 13 hours and requires a two-hour warm-up time. Cygnus, since the initial PMA was approved in 2001, has received various supplemental approvals, by the FDA, extending the age group from adults down to children aged 8 and older, allowing use with a topical ointment to reduce skin irritation, reducing the frequency of skipped readings, making the device less sensitive to perspiration, and reducing the warm-up time. The third generation GlucoWatch (G3)

Biographer has been approved by the FDA, but not yet commercialized.

The Medtronic CGMS system was approved by the FDA in 1999 and is the only system presently being sold by Medtronic. Although Medtronic s next generation product, the Guardian, received FDA approval in February 2004, it is not yet known when the Guardian System will become available commercially. Both the CGMS and the Guardian rely on a needle catheter containing a glucose-oxidase electrochemical sensor to measure blood glucose that has to be changed every three days. The Medtronic CGMS, a holter-type device, does not provide patients real-time blood glucose measured values, but rather it stores these values. The healthcare professional can download these values to obtain trending information. The CGMS requires four calibrations a day and retrospectively calibrates blood glucose readings. The Guardian System has, we believe, similar labeling to the GlucoWatch Biographer; that is, as an adjunctive use device that provides hypoglycemia alarms and blood glucose trending information. The Guardian requires at least two finger-stick tests of blood glucose a day to calibrate it. We also believe that Medtronic hopes to obtain approval from the FDA for the Guardian to transmit blood glucose readings via RF telemetry to their models 522/722 pumps.

A number of companies, in addition to Medtronic, are developing next-generation real-time continuous glucose monitoring or sensing devices and technologies. Progress on this front is difficult to assess, but we know that at least one other company, Abbott, has submitted a real-time continuous monitor for non-adjunctive use. It is unknown when, if ever, any continuous monitor or sensor, will be approved as a substitute for current glucose monitors or sensors.

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We believe that the principal competitive factors in our market include: technological superiority and leadership; strong acceptance by healthcare professionals and patients; high reliability, safety, and ease of use; intensive customer focus and service; comprehensive patient education; effective marketing and distribution; speed of product innovation; and agreements between third party payors and competitive brands.

Government Regulation

Our products are medical devices subject to extensive and ongoing regulation by the Food and Drug Administration (or FDA) and other regulatory bodies. FDA regulations govern product design and development, product testing, product manufacturing, product labeling, product storage, pre-market clearance or approval, advertising and promotion, product sales and distribution, and complaint handling, including providing reports to the FDA if a 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 it were to recur.

FDA s Pre-market Clearance and Approval Requirements. Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either a PMA or 510(k) clearance from the FDA. We have obtained 510(k) clearance for each of our insulin pumps. We expect that our long-term implantable continuous glucose sensor under development, as well as our MicroWatch will require a PMA.

> ***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 are placed in class III, requiring a PMA. A PMA application must be supported by extensive data, including technical, preclinical, 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. The Medical Device User Fee and Modernization Act (MDUFMA) provides a non-binding performance goal for PMA review by the FDA of 180 days in exchange for a designated application fee paid by the sponsor that may be several hundred thousand dollars.
>
> ***510(k) Clearance.*** To obtain 510(k) clearance for any of our products (or for certain modifications to devices that have received 510K 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 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 usually takes from three to six months from the date the application is completed, but can take significantly longer. The MDUFMA provides a non-binding performance goal for 510(k) review by the FDA of 75 days if more information is requested, and 90 days for final decisions in exchange for a designated application fee of several thousand dollars.

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, and civil or criminal penalties; recall or seizure of our products; operating restrictions, partial suspension, or total shutdown of production; refusing our request for 510(k) clearance or a PMA of new products; and withdrawing 510(k) clearance or PMAs that are already granted.

We are subject to announced and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors.

The FDA recently last inspected our facility for QSR compliance in October 2004. The audit resulted in a Form 483 citation. A Form FDA 483 consists of observations by an FDA investigator and does not constitute a final determination by the FDA regarding QSR compliance.

The observations include allegations that we have not ensured that an adequate and effective quality system has been fully

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implemented and maintained at all levels of our organization. Specifically, the FDA investigator observed instances in which we have not documented, evaluated, reported and trended complaints in a timely manner.

In November 2004, we sent the FDA a written response indicating the corrective actions that we have taken, and that we will take, in response to the FDA s observations. We received a Warning Letter, dated February 24, 2005, from the FDA, stemming from the October inspection. We responded to the FDA within the requisite 15-day time period, but have not yet received a response from the agency regarding the suitability of our responses.

The FDA is likely to conduct a reinspection of our facility to verify that we have corrected the alleged deviations. Although we believe that these corrective actions will adequately address the FDA observations, we cannot assure you that the FDA will agree or that it will find our written statement of completed and proposed corrective actions adequate, that upon reinspection the FDA will agree that corrective actions have been implemented adequately, or that the FDA will refrain from enforcement action based upon the current or future inspectional findings. The enforcement actions the FDA could take against us include issuance of a public warning letter, product recall or seizure, complete or partial shut down of our manufacturing operations, and the imposition of criminal and civil fines or penalties.

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 amongst the European Union, United States, Canada, and various other industrialized countries.

The primary regulatory environment in Europe is that of the European Union, which consists presently of 25 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third party assessment by a Notified Body. This third party assessment may consist of an audit of the manufacturer s quality system and specific testing of the manufacturer s product. Additionally, the European Union requires that the user guides of product imported into any European Union country must be in the native language(s) of each such country.

Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for use to market our products. In late 2004, we began distribution of the IR 1200 in Canada, Israel, France, Spain, Austria, Germany, United Kingdom, New Zealand, and Australia, upon receipt of regulatory approval of such country and/or satisfaction of regulatory requirements. We also expect to seek future distribution of the IR 1200 in the Czech Republic, Finland, Italy, and Hungary.

Licensure. Several states require that durable medical equipment (DME) providers be licensed in order to sell products to patients in that state. Certain of these states require that DME providers maintain an in-state location. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our 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.

Fee-splitting; Corporate Practice of Medicine. The laws of many states in which we maintain operations prohibit unlicensed persons or business entities, including corporations, from employing physicians and other health professionals or engaging in certain financial arrangements, such as splitting professional fees with non-physicians. These laws and their interpretations vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Possible sanctions for violations of these restrictions include loss of a licensure, civil and criminal penalties, and rescission of business arrangements that may violate these restrictions. We exercise care to structure our arrangements with healthcare providers to comply with the relevant state laws, and believe our current arrangements substantially comply with applicable laws. Government officials charged with responsibility for enforcing these laws may assert that we, or transactions in which we are involved, are in violation of such laws. Furthermore, such laws ultimately may be interpreted by the courts in a manner inconsistent with our interpretations.

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:

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the referral of a person;

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

the 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 generally provide the training and clinical services to patients necessary for appropriate use of our products. In a small percentage of the pumps that we sell, the providers provide the training and clinical services on our behalf and are reimbursed for these 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. 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. We believe that we are conforming to this law.

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 (HIPAA). 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.

In August 2000, the Department of Health and Human Services (DHHS) issued final regulations establishing electronic data transmission standards that healthcare providers must use when submitting or receiving certain healthcare data electronically. All affected entities, including us, were required to comply with these regulations by October 16, 2003.

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In December 2000, DHHS issued final regulations concerning the privacy of healthcare information, which were subsequently clarified in August 2002. These regulations regulate the use and disclosure of individuals healthcare information, whether communicated electronically, on paper, or verbally. All affected entities, including us, were required to comply with these regulations by April 2003. The regulations also provide patients with significant new rights related to understanding and controlling how their health information is used or disclosed.

In February 2003, DHHS issued final regulations concerning the security of electronic healthcare information and data. These regulations mandate the use of certain administrative, physical, and technical safeguards to protect the confidentiality of electronic healthcare information. Most affected entities, including us, are required to comply with these regulations by April 20, 2005.

In April 2003, DHHS issued interim final regulations related to the enforcement and imposition of penalties on entities that violate HIPAA standards. These regulations are the first installment of enforcement regulations which, when issued in complete form, will set forth procedural and substantive requirements for the enforcement and imposition of penalties under HIPAA. Sanctions include criminal penalties and civil sanctions.

We have established a plan and engaged the resources necessary to comply with HIPAA. At this time, we believe our operations are currently conducted in substantial compliance with those HIPAA regulations that are currently in effect. Based on the existing HIPAA regulations, we believe that the cost of our compliance with HIPAA will not have a material adverse effect on our business, financial condition, or results of operations.

Third Party Reimbursement

In the United States, our products are generally purchased directly by patients, distributors and, in some cases, military hospitals or managed care organizations. In many cases, on behalf of the patients, we bill third party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, other managed care providers, Medicare, and, to a limited extent, Medicaid. Under the Medicaid program, states generally reimburse for approved procedures on a reasonable cost or fee schedule basis. Currently, some states reimburse our products under the Medicaid program. Medicare provides a 15-month rental on insulin pumps and a fixed utilization of pump supplies.

We maintain an insurance assistance department consisting of approximately 60 people to simplify and expedite claims processing and to assist patients in obtaining third party reimbursement. We believe that over 95% of the net revenues from our insulin pumps and ancillary supplies are reimbursed by third party payors, subject to applicable deductible and co-payment amounts. Our business is affected by the reimbursement practices of third party payors. Many patients defer purchasing discretionary durable medical equipment, such as our insulin pumps, until they have satisfied their insurance deductibles which typically occur in the latter half of the calendar year.

Third party payors may decline to reimburse for procedures, supplies, or services determined not to be medically necessary or reasonable. In certain situations, some payors have declined to reimburse for a particular patient because such patient failed to meet the criteria. We try to deter and reverse such decisions through education and have expanded our insurance assistance efforts toward this end. Although our efforts are usually successful, such reimbursement may become less likely in the future as pressure increases for lower healthcare costs and 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 our products will save costs or will at least be cost effective is highly uncertain, and it is possible, especially for diabetes, that they will merely focus on the lower initial costs associated with injection therapy or will otherwise limit reimbursement for

insulin pumps 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 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 products would adversely affect our business and operating results.

Employees

As of December 31, 2004, we had 348 full-time equivalents, including 107 in field sales and sales administration, 8 in marketing, 77 in clinical, 66 in operations and manufacturing, 34 in engineering and research and development, 16 in quality assurance, and 40 in general and administrative functions. 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.

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WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information and periodic reporting requirements of the Exchange Act, and, in accordance with such requirements, are required to file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information are available for inspection and copying without charge at the public reference facilities maintained by the SEC in Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, and copies may be obtained from the SEC upon payment of the prescribed fee. Information on the operation of the public reference facilities may be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the site is http://www.sec.gov. You may also request copies of these filings, at no cost, by telephone at (610) 644-8990 or by mail to: Animas Corporation, 200 Lawrence Drive, West Chester, Pennsylvania 19380, Attention: Investor Relations or by accessing our website at http://www.animascorp.com.

Copies of our corporate governance policies, charters of our committees and our Code of Business Conduct and Ethics can be obtained free of charge by accessing our website.

Item 2. Properties

We have a 10-year lease expiring in 2014, with two five-year renewal options, for approximately 111,000 square feet of manufacturing, laboratory and office space at 200 Lawrence Drive in West Chester, Pennsylvania. We believe that our facility will be sufficient for the foreseeable future.

Item 3. Legal Proceedings

We are not currently subject to any material pending, or to our knowledge, threatened legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of 2004.

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PART II

Item 5. Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

We had our initial public offering on May 20, 2004. Our common stock is traded on the NASDAQ National Market under the symbol PUMP. On March 24, 2005, there were 149 registered stockholders of our common stock. Below is a summary of the high and low prices of our stock for each quarterly period since the date of our initial public offering as reported on the NASDAQ National Market. On March 24, 2005, the last sales price of our common stock was $20.88.

Period 2004	High	Low
Second quarter (since May 20, 2004)	$ 21.50	$ 16.65
Third quarter	$ 19.84	$ 12.08
Fourth quarter	$ 17.00	$ 13.36

Since our incorporation, we have never declared or paid any cash dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

On May 19, 2004, the Company s Registration Statement on Form S-1 covering the offering of 4,250,000 shares of the Company s common stock, Commission file number 333-113008 was declared effective (the Registration Statement). The offering closed on May 25, 2004 and did not terminate before any securities were sold. As of the date of the filing of this report, the offering has terminated. The offering was managed by Piper Jaffray & Co., J.P. Morgan Securities Inc. and Thomas Weisel Partners LLC as representatives of the several underwriters named in the Registration Statement (the Underwriters).

The Underwriters exercised an over-allotment option to purchase an additional 637,500 shares of the Company s common stock. The total price to the public for the shares offered and sold by the Company, including the over-allotment, was $73,312,500.

The amount of expenses incurred for the Company s account in connection with the offering is as follows:

Underwriting discounts and commissions	$ 5,131,875
Finders fees	
Expenses paid to or for the Underwriters	
Other expenses	2,435,264
Total expenses	$ 7,567,139

All of the foregoing expenses were direct or indirect payments to persons other than (i) directors, officers or their associates; (ii) persons owning ten percent (10%) or more of the Company s common stock; or (iii) affiliates of the Company

The net proceeds of the offering, including the exercise of the over-allotment option, to the Company (after deducting the foregoing expenses) were $65,745,361. From the effective date of the Registration Statement, the net proceeds

have been used for the following purposes:

Acquisition of Debiotech Technology	$ 12,241,076
Repayment of indebtedness	4,767,234
Working capital	19,015,099
Cash equivalents	29,721,952
	$ 65,745,361

All of the foregoing payments were direct or indirect payments to persons other than (i) directors, officers or their associates; (ii) persons owning ten percent (10%) or more of the Company s common stock; or (iii) affiliates of the Company.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

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Unregistered Securities

In October 2004, we issued 400,000 restricted shares of our common stock (the Shares) at $14.45 per share, pursuant to a Subscription Agreement, in connection with the acquisition of certain technology and intellectual property from Debiotech. These shares were valued at $5.8 million. The issuance and sale of the Shares to Debiotech were exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, because the issuance and sale did not involve any public offering. Under the Subscription Agreement, we also granted Debiotech certain piggyback registration rights which permit Debiotech to include the Shares on a registration statement to the extent we permit other holders of our common stock without contractual registration rights to participate in the same registration.

The information required by this item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

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Item 6. Selected Financial Data

The following consolidated statement of operations data for the years ended December 31, 2004, 2003 and 2002 and consolidated balance sheet data as of December 31, 2004 and 2003 have been derived from our audited consolidated financial statements and the related notes, which are included elsewhere in this report. The following consolidated statement of operations data for the years ended December 31, 2001 and 2000 and the consolidated balance sheet data as of December 31, 2002, 2001 and 2000 have been derived from our audited consolidated financial statements, which do not appear in this report. Certain amounts in the prior years have been reclassified to conform to the current year presentation. You should read this information in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes included elsewhere in this report.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Net revenues	$ 67,926	$ 34,120	$ 23,598	$ 10,040	$ 1,821
Operating expenses:					
Cost of products sold	26,986	16,759	12,384	8,578	1,983
Research and development expenses	6,301	5,173	3,921	2,492	2,737
Selling, general and administrative expenses	36,793	29,800	26,741	17,638	7,804
Purchased in-process research and development	14,521				
Total operating expenses	84,601	51,732	43,046	28,708	12,524
Loss from operations	(16,675)	(17,612)	(19,448)	(18,668)	(10,703)
Interest income	361	22	158	294	204
Interest expense	(348)	(214)	(84)	(127)	(153)
Net loss	(16,662)	(17,804)	(19,374)	(18,501)	(10,652)
Deemed dividend beneficial conversion feature of preferred stock		(7,878)[1]			
Net loss attributable to common stockholders	$ (16,662)	$ (25,682)	$ (19,374)	$ (18,501)	$ (10,652)
Basic and diluted net loss attributable to common stockholders per share	$ (1.23)	$ (6.64)	$ (5.02)	$ (4.80)	$ (2.88)
Weighted average shares basic and diluted	13,521,644	3,869,844	3,861,614	3,856,649	3,700,197

	As of December 31,

	2004	2003	2002	2001	2000
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 30,867	$ 384	$ 1,134	$ 16,607	$ 432
Working capital	56,646	4,164	5,312	17,223	(639)
Total assets	75,985	23,243	15,318	23,911	4,667
Long-term debt, net of current portion	254	467	852	178	281
Stockholders equity	65,006	7,303	7,462	19,346	397

(1)In connection with the issuances of preferred stock in 2003, we recorded a non-cash charge that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock. See Note 9 to our consolidated financial statements.

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read with our consolidated financial statements and related notes included elsewhere in this report. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including those set forth under Risk Factors and elsewhere in this report. Certain amounts in the prior years have been reclassified to conform to the current year presentation.

Overview

We design, develop, manufacture, and sell external insulin pumps for people with diabetes. We introduced our first generation pump in July 2000. We began shipping our third generation pump, the IR 1200, in April 2004 and in February 2005 began shipping the IR 1250. We also provide ancillary supplies necessary for pump therapy, including insulin cartridges, infusion sets, batteries, and various accessories.

Our approximately 55 person direct sales force promotes our pump in the United States to healthcare professionals and patients. In addition, our approximately 70 diabetes educators, or clinical managers, train and provide clinical support to patients in the United States. We also use domestic and international distributors to market, sell, and service our products.

Recent Developments

In May 2004, we completed our initial public offering (IPO) in which we sold 4,887,500 shares of our common stock at $15 per share. Net proceeds were approximately $65.7 million. As of the closing date of the offering, all of the convertible preferred stock previously outstanding was converted into 9,522,604 shares of common stock. A summary of the terms of this offering can be found in the Registration Statement on Form S-1 as filed with the Securities and Exchange Commission (Commission file number 333-113008).

In October 2004, we entered into license and development agreements with Debiotech for certain technology and intellectual property. We acquired the exclusive worldwide license to make, use, and sell products utilizing the intellectual property portfolio owned by Debiotech relating to micro-pumps and micro-needles for use related to insulin administration and in-vivo glucose sensing. We paid $12.0 million in cash and issued 400,000 restricted shares of our common stock for a total of $18.0 million; of which $14.5 million was charged to expense as purchased in-process research and development. The remaining $3.5 million has been classified as non current asset as a prepaid asset.

In December 2004, we announced that we had entered into a definitive agreement to acquire certain assets of Cygnus for $10.0 million in cash. The assets include substantially all of Cygnus intellectual property rights, fixed assets, supplier, manufacturing and license agreements, inventory and tangible personal property. On March 23, 2005, the stockholders of Cygnus, Inc. approved the transaction and the transaction was consummated. This transaction will be accounted as a purchase of assets and in-process research and development technology as the acquired assets do not constitute a business.

In December 2004, we received 510(k) clearance from the Food and Drug Administration to market the IR 1250 pump. The IR 1250 utilizes the IR 1200 platform but includes additional software which incorporates a food database of up to 500 items and tunes for alerts. We started shipping the IR 1250 in February 2005.

Financial Operations Overview

Net Revenues. We generate revenues primarily from the sale of our external insulin pumps and ancillary supplies, including insulin cartridges and infusion sets. In the year ended December 31, 2004, approximately 82% our products were sold directly to patients. We invoice patients either directly or through their healthcare payors, such as insurance companies and health maintenance organizations. Levels of reimbursement from healthcare payors vary depending upon the specific benefits provided under each patient s coverage. Net revenues for a particular product are the difference between the established billing rate for such product and the contractual allowance given to the healthcare payor.

Pump Upgrade Program. During the period November 1, 2003 to March 31, 2004 (the Period), we implemented a program that allowed patients in the United States, at their option and at no additional cost, to upgrade their IR 1000 pump purchased during the Period to the IR 1200 pump when it became available.

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In anticipation of the shipment of the IR 1200 in April 2004, we stopped domestic shipments of the IR 1000 for the last three weeks of March 2004. We began shipping the IR 1200 pump in April 2004. As of September 30, 2004, all obligations to ship upgrade pumps under this program were completed. At this time, we do not anticipate the need for additional product upgrade programs, of this nature, in the foreseeable future.

In accordance with U.S. generally accepted accounting principles, we deferred the recognition of all net revenues for IR 1000 pumps shipped under the upgrade program. We did not recognize the net revenue on an IR 1000 pump shipped under this program until either the IR 1200 replacement pump was shipped to the patient requesting an upgrade or the patient declined the upgrade. All IR 1000 pumps shipped to new patients domestically between November 1, 2003 and March 31, 2004 were subject to this upgrade program. We also deferred the associated cost of products sold on shipments of pumps under the upgrade program. Net revenues were recognized when we shipped the IR 1200 pump to the patient or when the patient declined to be part of the upgrade program. The deferred cost represented the estimated recoverable inventory costs of the IR 1000 pumps when they were returned to us. When we shipped an IR 1200 as a replacement pump, we recorded the cost of the IR 1200 pump as cost of products sold at that time.

As a result of this program, our net revenues for the year ended December 31, 2004 increased by the recognition of net revenues deferred from the previous year. The amount of deferred revenue recognized in 2004 was $4.7 million.

Cost of Products Sold. Cost of products sold include material costs, other direct and indirect manufacturing costs, shipping and handling costs, and product warranty expense. We purchase components and raw materials from third party vendors and assemble them into insulin pumps at our manufacturing facility in southeastern Pennsylvania. Insulin cartridges and certain other supplies are manufactured for us in Asia and Europe, as well as in the United States under agreements with third party suppliers. All purchases sourced from vendors or suppliers outside the United States are invoiced in U.S. dollars.

Direct and indirect manufacturing costs include material costs, labor costs, electricity and other utilities, maintenance expenses, depreciation and other fixed and variable costs required to operate our plant. Since the commercial introduction of our first pump in July 2000, the average unit cost of our pump has declined due to improved manufacturing efficiencies and increased absorption of fixed and semi-fixed overhead costs.

Like most of our competitors, we offer a four-year warranty on our pumps. Warranty expense is recorded in the period that product shipment occurs. The expense is based on historical experience and projected trends of warranty claims and the estimated cost to settle the claims.

Research and Development Expenses. Research and development expenses include costs associated with the design, development and testing of new and existing products. Such costs are charged to expense as incurred and include salaries and related personnel costs, fees paid to outside consultants, and other direct and indirect costs related to research and product development.

Selling, General and Administrative Expenses. Selling, general and administrative expenses include salaries, commissions and related personnel expenses for employees in sales, marketing, clinical, patient service and administrative functions, as well as overhead costs associated with these activities. Also included are costs associated with promotional literature and videos, trade show participation, education and training and the cost of providing demo pumps and supplies, which are charged to expense as incurred.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our significant accounting policies are more fully described in our accompanying consolidated financial statements. The critical accounting policies described below are those which we believe require estimates based on assumptions that are uncertain at the time the estimates are made, and for which different accounting estimates that management could have reasonably used would have had a material impact on reported financial information. Management has discussed the development and selection of our critical accounting estimates and related disclosures with the Audit Committee of our Board of Directors.

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Revenue Recognition. Revenues are generated primarily from the sale of insulin pumps and ancillary supplies. Customers do not have any right of return or any right to cancel or terminate the sale once the pumps or ancillary supplies are shipped. Pump and ancillary supplies net revenues are recognized upon shipment in accordance with Staff Accounting Bulletin No. 104 (SAB 104). In accordance with EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21), in instances where we provide pump operation training, we defer the fair value of the pump operation training until the training is delivered. We base the fair value of pump operation training on the historical amount we have paid to independent service providers for training patients on the operation of our pumps. Though the insulin pump has standalone value, there is no objective evidence as to the pump s fair value since we are reimbursed the same amount with or without pump operation training. As a result, the residual method under EITF 00-21 is utilized.

During the year ended December 31, 2004, approximately 82% of our products were sold directly to patients. We bill these patients directly or bill their healthcare payors. Levels of reimbursements from third party payors vary depending upon the specific benefits provided under each patient s coverage. At the time of sale, we record revenues net of third party contractual allowances, which represent the difference between the established billing rate and third party payor payments.

Net revenues for products sold directly to distributors are recognized upon shipment. Distributors have no right of return, and we have no post-shipment obligations.

Accounts Receivable/Allowance for Doubtful Accounts. In estimating the collectability of our accounts receivable, we analyze historical bad debts, payor concentrations, payor and patient credit-worthiness, current economic trends, and changes in patient and/or payor payment terms. These allowances are recorded in the period when the net revenues are recognized based on anticipated future events. If there are unanticipated future events, this allowance may need to be adjusted.

Inventories. Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Costs for pumps include material, labor, and manufacturing overhead. Ancillary supplies inventory and raw materials inventory include material costs only. We review our inventory balances monthly for obsolete inventory. We manage the risk of inventory obsolescence through validating product designs prior to product introduction, as well as through planning of inventory with respect to anticipated design changes. Once inventory is determined to be obsolete, the inventory is charged to cost of products sold, removed from our stockroom, and either scrapped or used for non-inventory purposes.

Deferred Tax Asset Valuation Allowance. Our estimate for the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about our future operating results. Our ability to realize the deferred tax assets depends on our future taxable income as well as limitations on their utilization. A deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of our operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for our products, competitive conditions, product development efforts, approvals of regulatory agencies and product cost. If actual results differ from these projections, or if our expectations of future results change, it may be necessary to adjust the valuation allowance. As a result of the historic losses, the Company has provided a full valuation allowance for the deferred tax assets.

Warranty Liability. Each of our insulin pumps is sold with a four-year warranty. Our warranty liability represents the total estimated cost for expected future warranty claims related to all products shipped. Warranty expense is accrued in the period that the products are shipped and is based on historical experience, projected trends of warranty claims, and the expected costs to settle the claims. As changes occur in expected warranty claim rates and the estimated cost to settle claims, the warranty liability is adjusted accordingly.

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Years Ended December 31, 2004 and 2003

Results of Operations. The following tables set forth, for the years indicated, certain operational information. A percentage breakdown of net revenues is presented for certain operational items. The breakdown of cost of products sold and gross margin is presented as a percentage of these respective items.

	Years Ended December 31,					
	2004		2003		Change, 2004/2003	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$ 67,926	100.0%	$ 34,120	100.0%	$ 33,806	99.1%
Operating expenses:						
Cost of products sold	26,986	39.7	16,759	49.1	10,227	61.0
Research and development expenses	6,301	9.3	5,173	15.2	1,128	21.8
Selling, general and administrative expenses	36,793	54.2	29,800	87.3	6,993	23.5
Purchased in-process research and development	14,521	21.3			14,521	
Total operating expenses	84,601	124.5	51,732	151.6	32,869	63.5
Loss from operations	(16,675)	(24.5)	(17,612)	(51.6)	937	5.3
Interest income	361	0.5	22	0.1	339	1,540.9
Interest expense	(348)	(0.5)	(214)	(0.7)	(134)	(62.6)
Net loss	(16,662)	(24.5)	(17,804)	(52.2)	1,142	6.4
Deemed dividend			(7,878)	(23.1)	7,878	100.0
Net loss attributable to common stockholders	$ (16,662)	(24.5)%	$ (25,682)	(75.3)%	$ 9,020	35.1%

	Years Ended December 31,					
	2004		2003		Change, 2004/2003	
	$	%	$	%	$	%
	(in thousands)					
Net Revenues, Cost of Products Sold and Gross Margin						
Net revenues (dollars and as a percent of total)						

Insulin pumps	$ 47,178	69.5%	$ 21,176	62.1%	$ 26,002	122.8%
Ancillary supplies	20,748	30.5	12,944	37.9	7,804	60.3
Total	$ 67,926	100.0%	$ 34,120	100.0%	$ 33,806	99.1%
Cost of products sold (dollars and as a percent of total)						
Insulin pumps	$ 14,639	54.2%	$ 8,462	50.5%	$ 6,177	73.0%
Ancillary supplies	12,347	45.8	8,297	49.5	4,050	48.8
Total	$ 26,986	100.0%	$ 16,759	100.0%	$ 10,227	61.0%
Gross margin (dollars and as a percent of total)						
Insulin pumps	$ 32,539	79.5%	$ 12,714	73.2%	$ 19,825	155.9%
Ancillary supplies	8,401	20.5	4,647	26.8	3,754	80.8
Total	$ 40,940	100.0%	$ 17,361	100.0%	$ 23,579	135.8%

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	Years Ended December 31,	
	2004	2003
Gross margin % (as a percent of net revenues)		
Insulin pumps	69.0%	60.0%
Ancillary supplies	40.5%	35.9%
Total	60.3%	50.9%

Net Revenues. In 2004, net revenues were $67.9 million, compared to $34.1 million in 2003. Of the increase in net revenues, $21.3 million was primarily from increased demand for pumps, $7.8 million from increased shipments of ancillary supplies and $4.7 million from the recognition of revenue deferred in prior periods associated with the pump upgrade program. Net revenues from domestic and foreign sales were $63.0 million and $4.9 million, respectively, in 2004 and $31.7 million and $2.4 million, respectively, in 2003. Pump net revenues increased by $26.0 million primarily due to increases in unit shipments due to the continued strong demand for the IR 1200 and the positive international launch of the IR 1200, particularly in Germany, France and Canada. Our average selling price of pumps remained relatively stable over this period.

Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges and other ancillary supplies increased by 60.3% in 2004 versus the comparable period of 2003. The increase was due to increased unit sales, while prices remained near prior period levels. The growth also reflected our growth in the number of patients using our pumps in 2004 and our retention of patients from prior years.

We anticipate net revenues for pumps and ancillary supplies to continue to increase in 2005 as we further expand internationally and grow the ancillary supplies market.

Cost of Products Sold. Cost of products sold increased by $10.2 million, or 61.0%, to $27.0 million in 2004 from $16.8 million in 2003 primarily due to the increase in net revenues in 2004. However, as a percentage of net revenues, cost of products sold decreased to 39.7% in 2004 from 49.1% in 2003. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies for supplies and pump materials, and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by $6.2 million, or 73.0% in 2004 as compared to 2003. The rate of this increase was lower than the rate of increase of pump sales due to the economies and efficiencies described above, which offset the additional costs associated with the production ramp-up of the IR 1200 incurred during the third quarter of 2004 and the $1.0 million of additional costs associated with the additional pumps shipped under the pump upgrade program.

Gross Margin. Gross margin increased to 60.3% in 2004 from 50.9% in 2003. Gross margin for pumps increased to 69.0% in 2004 from 60.0% in 2003 due to better absorption of overhead associated with increased sales volume and lower cost of raw materials. The pump upgrade program had a slightly positive impact on the gross margin for pumps in 2004. Ancillary supplies gross margin increased to 40.5% in 2004 from 35.9% in 2003. Gross margin improvement for ancillary supplies was due to lower cost sources of supply.

It is anticipated that the gross margin and gross margin percentage will continue to improve in 2005. Reasons for this improvement include the introduction of our ezSet infusion system further reductions of the costs of our existing disposables, and increased absorption of manufacturing overheads.

Research and Development. Research and development expenses increased $1.1 million, or 21.8%, to $6.3 million in 2004 from $5.2 million in 2003 reflecting increased spending on activities to improve existing products and develop new products. As a percentage of net revenues, research and development expenses decreased to 9.3% in 2004 from

15.2% in 2003.

Although we anticipate a similar increase in research and development costs in 2005 from 2004 as compared to the increase in 2004 from 2003, we also anticipate a decrease in these costs as the percentage of net revenues. In 2005, we expect approximately 80% of our research and development budget to be allocated to the development of next generation pumps and ancillary supplies. We expect future net revenues from these products to supplant net revenues from existing products. The remaining approximately 20% of our research and development budget in 2005 is allocated towards development of long-term products, including micro-needles and continuous glucose sensors.

Selling, General and Administrative (SG&A) Expenses. SG&A expenses increased by $7.0 million, or 23.5%, to $36.8 million in 2004 from $29.8 million in 2003. However, as a percentage of net revenues, SG&A expenses decreased to 54.2% in 2004 from 87.3% in 2003.

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Of the increase, $3.4 million was primarily related to higher costs principally associated with increased headcount in the sales, clinical, and marketing functions supporting increased selling activity for existing pumps and ancillary supplies, as well as the launch of the IR 1200 and IR 1250. In addition, higher insurance costs of $1.2 million, administrative personnel costs of $575,000, professional fees of $409,000, depreciation expense of $290,000, and rent expense of $257,000 contributed to higher SG&A costs in 2004. The remaining increase is primarily attributable to increased marketing and promotional expenses and general and administrative expenses associated with operating as a public company.

We expect SG&A expenses to increase in absolute dollars in 2005 from 2004 as we expand our sales, clinical, and marketing efforts to support our growing business. However, we expect that SG&A expenses should continue to decline as a percent of net revenues as we continue to leverage our existing SG&A infrastructure.

Purchased in-process research and development. In October 2004, we entered into license and development agreements with Debiotech for certain technology and intellectual property. We paid $12.0 million in cash and issued 400,000 restricted shares of common stock, of which $14.5 million was immediately charged to expense to purchased in-process research and development and $3.5 million was recorded as a non-current asset. The amount capitalized, upon project success, will be evaluated and will either be charged to expense ratably over the life of the technology or will be expensed as in-process research and development. If the project is not successful, then the full amount of the $3.5 million fee will be refunded to us.

Interest Income. Interest income increased to $361,000 in 2004 from $22,000 in 2003. The increase was primarily due to a higher investment balance as a result of the initial public offering in May 2004.

Interest Expense. Interest expense increased to $348,000 in 2004 from $214,000 in 2003. This reflects a higher outstanding debt balance than in the comparable period. The increase in average debt was primarily the result of higher borrowing under our credit lines during the first half of 2004 before completion of the initial public offering.

Income Taxes. We have incurred net operating losses since inception and, as a result, we have paid no state or federal income taxes. As of December 31, 2004, we had $76.5 million in federal net operating loss carryforwards, which begin to expire in 2017, that are available to reduce future taxable income. We also have $45.0 million of state carryforwards that are subject to annual limitations and begin to expire in 2007. The federal and state carryforwards may be subject to annual utilization limitations under Internal Revenue Code Section 382 due to certain of our equity transactions that have resulted in substantial changes in ownership. Due to the uncertainty of our ability to generate sufficient taxable income to realize the carryforwards prior to their expiration, we have established valuation allowances at December 2004 and 2003 to fully offset the deferred tax assets.

Deemed Dividend Beneficial Conversion Feature of Preferred Stock. In connection with issuances of preferred stock in 2003, we recorded a non-cash charge of $7.9 million that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock. There was no similar item in 2004.

Net Loss Attributable to Common Stockholders. We reported a net loss of $16.7 million in 2004 as compared to a net loss of $25.7 million in 2003.

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Years Ended December 31, 2003 and 2002

Results of Operations. The following tables set forth, for the years indicated, certain operational information. A percentage breakdown of net revenues is presented for certain operational items. The breakdown of cost of products sold and gross margin is presented as a percentage of these respective items.

	Years Ended December 31,					
	2003		2002		Change, 2003/2002	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$ 34,120	100.0%	$ 23,598	100.0%	$ 10,522	44.6%
Operating expenses:						
Cost of products sold	16,759	49.1	12,384	52.5	4,375	35.3
Research and development expenses	5,173	15.2	3,921	16.6	1,252	31.9
Selling, general and administrative expenses	29,800	87.3	26,741	113.3	3,059	11.4
Total operating expenses	51,732	151.6	43,046	182.4	8,686	20.2
Loss from operations	(17,612)	(51.6)	(19,448)	(82.4)	1,836	9.4
Interest income	22	0.1	158	0.7	(136)	(86.1)
Interest expense	(214)	(0.7)	(84)	(0.4)	(130)	(154.8)
Net loss	(17,804)	(52.2)	(19,374)	(82.1)	1,570	8.1
Deemed dividend	(7,878)	(23.1)			(7,878)	(100.0)
Net loss attributable to common stockholders	$ (25,682)	(75.3)%	$ (19,374)	(82.1)%	$ (6,308)	(32.6)%

	Years Ended December 31,					
	2003		2002		Change, 2003/2002	
	$	%	$	%	$	%
	(in thousands)					
Net Revenues, Cost of Products Sold and Gross Margin						
Net revenues (dollars and as a percent of total)						
Insulin pumps	$ 21,176	62.1%	$ 17,763	75.3%	$ 3,413	19.2%
Ancillary supplies	12,944	37.9	5,835	24.7	7,109	121.8

Total	$ 34,120	100.0%	$ 23,598	100.0%	$ 10,522	44.6%
Cost of products sold (dollars and as a percent of total)						
Insulin pumps	$ 8,462	50.5%	$ 8,080	65.2%	$ 382	4.7%
Ancillary supplies	8,297	49.5	4,304	34.8	3,993	92.8
Total	$ 16,759	100.0%	$ 12,384	100.0%	$ 4,375	35.3%
Gross margin (dollars and as a percent of total)						
Insulin pumps	$ 12,714	73.2%	$ 9,683	86.3%	$ 3,031	31.3%
Ancillary supplies	4,647	26.8	1,531	13.7	3,116	203.5
Total	$ 17,361	100.0%	$ 11,214	100.0%	$ 6,147	54.8%

	Years Ended December 31,	
	2003	2002
Gross margin % (as a percent of net revenues)		
Insulin pumps	60.0%	54.5%
Ancillary supplies	35.9%	26.2%
Total	50.9%	47.5%

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Net Revenues. Net revenues increased $10.5 million, or 44.6%, in 2003 to $34.1 million from $23.6 million in 2002. The increase was caused by the growth in the overall market for insulin pumps, an increase in our share of both the domestic and foreign markets in which we participate, and our larger installed base of patients using our pumps. Net revenues from domestic and foreign sales were $31.7 million and $2.4 million, respectively, in 2003 and were $23.0 million and $592,000, respectively, in 2002. Pump net revenues increased 19.2% from the prior year. The increase in pump net revenues reflected an increase in unit shipments, while selling prices were comparable to prior year levels. Ancillary supplies net revenues, consisting of infusion sets, pump cartridges, and other ancillary supplies, increased 121.8% in 2003 from the prior year. Our average selling price of pumps remained relatively stable over this period. The increase in net revenues for supplies was also due to increased unit sales, while prices remained near prior year levels. The large growth in net revenues in ancillary supplies reflected our growth in the installed base of patients using our pump in 2003 compared to 2002 and our retention of patients from prior years.

In November 2003, we implemented a program that permitted patients in the United States, at their option and at no additional cost, to upgrade their purchase of the IR 1000 insulin pump to the IR 1200 insulin pump when it became available. All pumps sold in the United States between November 1, 2003 and March 31, 2004 were subject to this upgrade program. In accordance with SAB 104, we deferred the recognition of net revenues on such shipments of IR 1000 pumps due to the upgrade obligation. As of December 31, 2003, we recorded deferred net revenues of $4.7 million and the related cost associated with deferred revenue of $1.0 million.

Cost of Products Sold. Cost of products sold increased $4.4 million, or 35.3%, to $16.8 million in 2003 from $12.4 million in 2002, reflecting the increase in net revenues in 2003 from 2002. However, as a percent of net revenues, cost of products sold declined to 49.1% in 2003 from 52.5% in 2002. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies for supplies and pump materials, better manufacturing yields of our pumps, and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by $382,000, or 4.7%, in 2003 as compared to 2002. The rate of this increase was lower than the rate of increase of pump sales due to the economies and efficiencies described above. In addition, our strong focus on quality control and assurance resulted in reduced scrap and product rework costs in 2003 compared to 2002.

Gross Margin. Gross margin improved to 50.9% in 2003 from 47.5% in 2002. Gross margin for pumps improved to 60.0% in 2003 from 54.5% in 2002. Gross margin improvement for pumps was caused by increases in sales volume, better absorption of overhead, improved yields, and lower cost of raw materials. Ancillary supplies gross margin increased to 35.9% in 2003 from 26.2% in 2002. Gross margin improvement for ancillary supplies was due to lower cost sources of supplies.

Research and Development. Research and development expenses increased $1.3 million, or 31.9%, to $5.2 million in 2003 from $3.9 million in 2002 reflecting increased spending on activities to improve existing products and develop new products. As a percentage of net revenues, research and development expenses declined to 15.2% in 2003 from 16.6% in 2002 due to the significant increase in net revenues in 2003 from the prior year.

Selling, General and Administrative Expenses. SG&A expenses increased $3.1 million, or 11.4%, to $29.8 million in 2003 from $26.7 million in 2002. Of this increase, $1.8 million was primarily related to higher costs principally associated with increased headcount in the sales, clinical, and marketing functions supporting the significant increase in sales activity from 2002. These costs were required to accomplish the increase in net revenues and the increased requirements for educational support and training programs. In addition, higher administrative personnel costs ($343,000), commercial insurance ($390,000), and bad debts ($572,000), all of which reflect the growth in our volume from 2002 to 2003, contributed to the increase in such costs. As a percent of net revenues, SG&A costs in 2003 declined to 87.3% of net revenues from 113.3% from 2002. This decline was largely due to our continuing ability to gain economies of scale related to our significant growth in net revenues.

Interest Income. Interest income declined to $22,000 in 2003 from $158,000 in 2002 reflecting lower average cash and cash equivalents balances in 2003.

Interest Expense. Interest expense increased to $214,000 in 2003 from $84,000 in 2002 reflecting a higher average outstanding debt balance in 2003 as compared to 2002. The increase in average debt was primarily the result of higher borrowing under our credit lines and a $1.0 million note payable that was issued to a bank in November 2002 and is payable in monthly installments of $28,000 through November 2005.

Income Taxes. We have incurred net operating losses since inception and, as a result, we have paid no state or federal income taxes. As of December 31, 2003, we had $63.9 million in federal net operating loss carryforwards that are

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available to reduce future taxable income. We also had $34.4 million of state carryforwards that are subject to annual limitations. The federal and state carryforwards may be subject to annual utilization limitations under Internal Revenue Code Section 382 due to certain of our equity transactions that have resulted in substantial changes in ownership. Due to the uncertainty of our ability to generate sufficient taxable income to realize the carryforwards prior to their expiration, we have established valuation allowances at December 2003 and 2002 to fully offset the deferred tax assets.

Deemed Dividend Beneficial Conversion Feature of Preferred Stock. In connection with issuances of preferred stock in 2003, we recorded a non-cash charge of $7.9 million that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock (see Note 9 to our consolidated financial statements).

Net Loss Attributable to Common Stockholders. We reported a net loss of $25.7 million in 2003 as compared to a net loss of $19.4 million in 2002.

Seasonality and Quarterly Results

Our business is affected by the reimbursement practices of third party payors. Many patients defer purchasing discretionary durable medical equipment, such as our insulin pumps, until they have satisfied their insurance deductibles which typically occur in the latter half of the calendar year.

Quarterly Results

	2004				2003			
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
	(in thousands except per share data)							
Net revenues	$ 4,837	$ 20,420	$ 22,654	$ 20,015	$ 7,380	$ 9,205	$ 11,291	$ 6,244
Gross margin	1,896	13,083	13,988	11,973	3,891	4,707	6,859	1,904
Net income (loss)	(8,084)	2,636	2,819	(14,033)	(4,470)	(4,704)	(2,212)	(6,418)
Deemed dividend					(4,911)	(152)		(2,815)
Net income (loss) attributable to common stockholders	$ (8,084)	$ 2,636	$ 2,819	$ (14,033)	$ (9,381)	$ (4,856)	$ (2,212)	$ (9,233)
Basic net income (loss) attributable to common stockholders per share	$ (2.01)*	$ 0.24	$ 0.15	$ (0.71)	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)
Diluted net income (loss) attributable to common stockholders per share	$ (2.01)*	$ 0.14	$ 0.14	$ (0.71)	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)

*Basic and diluted net loss per share has been revised from ($2.07).

Net revenues increased from $7.4 million in the first quarter of 2003 to $11.3 million in the third quarter of 2003. In the fourth quarter of 2003 and the first quarter of 2004, our net revenues decreased due to our deferral of $4.7 million

and $4.5 million of net revenues, respectively, resulting from the pump upgrade program initiated in November 2003. Additionally, our net revenues, in the first quarter of 2004, were impacted by our decision to stop shipment of pumps for the last three weeks in March 2004 in anticipation of the launch of the IR 1200 in April 2004. Revenue for the second quarter of 2004 benefited from the shipment of $2.3 million in revenue delayed at the end of the first quarter and an additional $3.7 million of revenue previously deferred as a result of the pump upgrade program and due to increased demand for our pumps and ancillary supplies. Revenue for the third quarter of 2004 benefited from $5.5 million of revenue previously deferred as a result of the pump upgrade program and due to increased demand for our pumps and ancillary supplies. Net revenue in the fourth quarter of 2004 fell slightly, despite increased demand, as we completed the upgrade program during the third quarter of 2004 and there was no recognition of revenues previously deferred from prior periods.

Gross margin improved from 52.7% in the first quarter of 2003 to 60.7% in the third quarter of 2003. The gross margin for the fourth quarter of 2003 and the first quarter of 2004 dropped to 30.5% and 39.2%, respectively, due to the deferral of net revenues and associated costs due to the upgrade program and the decision to stop shipments of pumps for the last three weeks of March 2004. The gross margin in the second quarter of 2004 increased to 64.1% as a result of the increased absorption of overhead due to the increased volume of pumps from the pump upgrade program and the shipment in the second quarter of the unfulfilled orders from the first quarter which combined contributed 3.7% to the improvement of gross margins. Gross margin in the third quarter of 2004 was 61.7% which reflected a benefit of approximately 4.9% from the increased volume of the pump upgrade program and a decrease due to additional costs of approximately $439,000 due to increased costs associated with production ramp-up of the IR 1200. Gross margin in the fourth quarter of 2004 was 59.8%, with no benefit from the pump upgrade program as our obligation was completed in September 2004.

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Net loss before deemed dividend declined from $4.5 million in the first quarter of 2003 to $2.2 million in the third quarter of 2003. Net loss increased in the fourth quarter of 2003 and the first quarter of 2004 to $6.4 million and $8.1 million, respectively, due to the pump upgrade program and the resulting deferral of net revenues and associated costs. Additionally, the net loss was increased due to our decision to stop the shipment of pumps for the last three weeks of March 2004. In the second quarter of 2004, net income increased to $2.6 million. This was the result of additional revenue associated with the shipment of additional pumps due to the pump upgrade program, the shipment in the second quarter of the unfulfilled orders from the first quarter and the increased demand. Net income increased to $2.8 million in the third quarter of 2004 due to the additional revenue associated with the shipment of additional pumps due to the pump upgrade program and the increased demand for both pumps and ancillary supplies. The net loss in the fourth quarter of 2004 was due to the write-off of purchased in-process research and development of $14.5 million.

The deemed dividend was caused by the sale of preferred stock and warrants from January through April and in November 2003. The deemed dividend in 2003 increased the net loss attributable to common stockholders for the year ended December 31, 2003. Additional losses due to deemed dividends in 2004 are not anticipated.

Liquidity and Capital Resources

Historically, we have funded our operations primarily through the sale of equity securities yielding net proceeds of $79.9 million through the quarter ended March 31, 2004. On May 25, 2004, we closed our IPO of 4,250,000 shares of our common stock at $15 per share. Additionally, the underwriters exercised the over-allotment option for the purchase of 637,500 additional shares of our common stock at the offering price of $15. Net proceeds, including the exercise of the over-allotment option, were approximately $65.7 million.

In addition, we have funded our operations through lines of credit and long-term debt and lease financing. We currently have one line of credit with a bank, totaling $6.0 million, of which no amount was outstanding at December 31, 2004. We also have an equipment lease financing loan of $238,000 outstanding at December 31, 2004.

Cash Used in Operating Activities. Cash used in operating activities was $17.7 million and $18.2 million for the years ended December 31, 2004 and 2003, respectively. The major use of cash during 2004 was primarily for increased working capital and the funding of the loss of $16.7 million, which included the write-off of $14.5 million of purchased in-process research and development. The major use of cash during 2003 was to fund the loss of $17.8 million. Accounts receivable increased by $10.5 million during 2004 due primarily to the growth of our business, the extension of and the expansion of credit terms to certain distributors, and increased sales to Medicare and Medicaid patients, which are traditionally slow payment payors. Our inventory increased by $7.6 million during 2004 due primarily to the growth of our business and the introduction of the IR 1200.

The pump upgrade program had a negative effect on our cash flows. During the quarter ended December 31, 2003, the pump upgrade program did not have a negative effect on liquidity as we billed upon the shipment of all pumps subject to the upgrade program. However, as we shipped the IR 1200 replacement pumps during the second and third quarters of 2004, we did not generate any additional cash with these shipments. As a result, in 2004, our cash flows from operating activities were negatively affected by the increase of inventory associated with IR 1000 pumps returned under the upgrade program.

Cash Used in Investing Activities. Cash used in investing activities was $17.0 million and $1.5 million for the years ended December 31, 2004 and 2003, respectively. The major use of cash during 2004 was primarily for the Debiotech acquisition. Additionally, investing activities consisted of the purchase of approximately $4.8 million and $1.5 million of capital expenditures for the years ended December 31, 2004 and 2003, respectively. The capital expenditures were primarily for manufacturing equipment and computer equipment to support the significant growth in our business

during that period and to position us for expected growth in 2004 and beyond.

Cash Provided by Financing Activities. Net cash provided by financing activities was $65.2 million and $18.9 million for the years ended December 31, 2004 and 2003, respectively. The net cash provided by financing activities during 2004 was primarily due to our IPO which raised net proceeds of $65.7 million. These amounts were partially offset by the repayment of debt. The net cash provided by financing activities during 2003 was primarily due to proceeds of $16.7 million from the sale of preferred stock.

Bank Credit Facilities. We have a line of credit with a bank under which we can borrow a maximum of $6.0 million at an interest rate of 1.75% above the bank s prime rate. This line of credit contains a debt covenant that requires that we maintain a certain net worth throughout the term of this line of credit. We were in compliance with this covenant at December 31, 2004. Borrowings under this facility are limited to 75% of our eligible accounts receivable, which generally consist of our accounts receivable that are less than 120 days old and 25% of our eligible inventory. Borrowings are secured by a pledge of substantially all of our assets. As of December 31, 2004, there was no amount outstanding on this line of credit.

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Equipment Financing. In November 2002, we entered into an equipment lease loan with a bank for $1.0 million. This loan bears interest at a rate of 1.5% above the prime rate and matures on November 4, 2005. The principal is paid in monthly installments of $28,000. As of December 31, 2004, the principal amount outstanding was $238,000.

Operating Leases. At December 31, 2004, commitments related to future lease payments under operating leases, are $1.1 million in 2005, $1.2 million in 2006, $1.2 million in 2007, $1.2 million in 2008, $1.3 million in 2009 and $5.7 million beyond 2009. There were no material commitments related to future capital expenditures on approved projects at December 31, 2004. At December 31, 2004, we had $550,000 outstanding on a letter of credit for a security deposit on the lease for our new facility.

As of December 31, 2004, we had cash and cash equivalents of $30.9 million. We expect to have negative cash flows for 2005 resulting primarily from the $10.0 million acquisition of the Cygnus technology. Additionally, we expect increased selling and administrative expenses as well as we continue to increase spending for personnel and infrastructure improvement. We believe that our current cash, line of credit, and any cash generated from our operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into 2006 and the foreseeable future. If existing cash and any cash generated from operations are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity or debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and sales and marketing efforts.

Contractual Obligations. The table below identifies payment obligations for the periods indicated under our contractual obligations as of December 31, 2004. The amounts set forth below reflect the current contractual obligations and do not reflect managements expectations as to expenditures for the categories of obligations described below during the periods identified below. The timing and/or the amount of the payments may be altered in accordance with the terms of the contracts or new contractual obligations may be added. Examples of changes that may occur are:

A contract is terminated prior to its expiration date or extended beyond the original date;

New leases are added; or

New lines of credit or term loans are added.

Contractual Obligations

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
			(in thousands)		
Lease financing:					
Operating lease obligations	$ 1,146	$ 2,364	$ 2,483	$ 5,680	$ 11,673
Capital lease obligations	201	234	61		496
Purchase obligations[(1)]	7,700	20,400	22,998		51,098
Letter of credit	550				550
Long-term borrowings:					
Equipment note bank	238				238

Total obligations	$ 9,835	$ 22,998	$ 25,542	$ 5,680	$ 64,055

(1) We have assumed that the required materials will generally remain consistent with prior years. The amount of the obligation is based on future installed base numbers that are currently unknown.

Inflation

Inflation has not had a significant impact on our operations over the past three years and we do not expect it to have a significant impact on the results of operations or financial condition in the foreseeable future.

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Recent Accounting Pronouncement

In November 2004, the FASB issued SFAS No. 151 (SFAS 151), Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material should be recognized as current period charges and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. SFAS 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Early adoption is permitted for inventory costs incurred during fiscal years beginning after the date SFAS 151 was issued. SFAS 151 should be applied prospectively. We do not expect the adoption of this standard to have a material impact on our consolidated financial position, results of operations and cash flows.

In December 2004, the FASB issued SFAS No. 123(R) (SFAS 123 (R), Share-Based Payment. SFAS 123(R) revises SFAS 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS 123(R) will require compensation costs related to share-based payment transactions to be recognized in the financial statements (with limited exceptions). The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. This statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The full impact of adoption of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and loss per share in Note 2 of the notes to the consolidated financial statements. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We are unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

RISK FACTORS

We are a medical device company and our products and processes are regulated and monitored by the FDA and by foreign regulators. If we fail to comply with any FDA or foreign regulations, our business may be harmed. We recently received a Warning Letter from the FDA resulting from an inspection of our facility for compliance with the FDA Quality Systems Regulation (QSR) in October 2004. The FDA made a number of observations of alleged QSR deviations. The FDA could bring an enforcement action against us resulting in the issuance of a public warning letter, product recall or seizure, complete or partial shutdown of our manufacturing operations, and the imposition of criminal and civil fines or penalties, which would adversely affect our net revenues and our future profitability.

Quality Systems Regulation. The manufacturing processes for our pumps, cartridges, and infusion sets are required to comply with the FDA s QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of our products. The FDA enforces the QSR through announced or unannounced inspections.

The FDA recently last inspected our facility for QSR compliance in October 2004. The audit resulted in a Form 483 citation. A Form FDA 483 consists of observations by an FDA investigator and does not constitute a final determination by the FDA regarding QSR compliance.

The observations include allegations that we have not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of our organization. Specifically, the FDA

investigator observed instances in which we have not documented, evaluated, reported and trended complaints in a timely manner.

In November 2004, we sent the FDA a written response indicating the corrective actions that we have taken, and that we will take, in response to the FDA s observations. We received a Warning Letter, dated February 24, 2005, from the FDA, stemming from the October inspection. We responded to the FDA within the requisite 15-day time period, but have not yet received a response from the agency regarding the suitability of our responses.

The FDA is likely to conduct a reinspection of our facility to verify that we have corrected the alleged deviations.

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Although we believe that these corrective actions will adequately address the FDA observations, we cannot assure you that the FDA will agree or that it will find our written statement of completed and proposed corrective actions adequate, that upon reinspection the FDA will agree that corrective actions have been implemented adequately, or that the FDA will refrain from enforcement action based upon the current or future inspectional findings. The enforcement actions the FDA could take against us include issuance of a public warning letter, product recall or seizure, complete or partial shut down of our manufacturing operations, and the imposition of criminal and civil fines or penalties.

The manufacturing line for our cartridge vendor has not been inspected to date. If our third party cartridge vendor or our original equipment manufacturer supplier of our infusion sets fails a QSR, our operations could be disrupted and our production delayed.

Product Recalls. The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design, manufacture, or quality systems. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, or design defects in any of our products. Any recall of our products would divert managerial and financial resources and harm our reputation with patients, healthcare providers, and payors, as well as reduce our net revenues and future profitability.

New Products 510(k) Clearances or Pre-market Approvals. Our products are medical devices that are subject to extensive regulation in the United States and in foreign countries where we do business. Unless an exemption applies, each medical device that we market in the United States must first receive either 510(k) clearance or PMA from the FDA. Either process can be lengthy and expensive. The FDA s 510(k) clearance process usually takes from three to six months from the date the application is completed and accepted for filing by the FDA, but may take longer. Although we have obtained 510(k) clearance for our insulin pumps, our 510(k) clearance can be modified or revoked if safety or effectiveness problems develop. The PMA process is much more costly, lengthy, and uncertain. It generally takes from one to three years from the date the application is completed and accepted for filing by the FDA. However, achieving a completed application is a process that may take numerous clinical trials and require the filing of amendments over time. We expect that our continuous glucose sensor under development will require a PMA. Therefore, even if the product is successfully developed, it may not be commercially available for a number of years. We may not be able to obtain additional clearances or approvals in a timely fashion, or at all. Delays in obtaining clearances or approvals could adversely affect our net revenues and future profitability.

Product Modifications New 510(k) Clearances or PMAs. Any modification to a FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review and disagree with any such decision. We modified aspects of the IR 1200 since receiving regulatory clearance, but believe that new 510(k) clearances are not required. We may make additional modifications to the IR 1200 and future products after they have received clearance or approval, and in appropriate circumstances, determine that new clearance or approval is unnecessary. If the FDA subsequently requires us to seek 510(k) clearances or PMA supplements for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified product until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

Medical Device Reporting. The FDA requires manufacturers to file Medical Device Reports (MDRs) upon receiving reports of device malfunction or serious or life threatening injury that may have been caused by the medical device. MDRs have been filed with the FDA for the R1000, IR 1000 and IR 1200 insulin pumps.

Based upon the FDA s review of MDRs, the agency can require additional labeling, physician or consumer notification, recalls, or redesign. Any such regulatory action by the FDA could cause our net revenues and future profitability to suffer.

Advertising and Promotion. Our sales force promotes and markets our products using a variety of accepted sales tactics including sampling, physician visits, advertisements, marketing literature, and an Internet website. While our promotional practices and materials are carefully screened and reviewed internally, the FDA may deem information to exceed approved labeling or to be false and misleading. It may request that promotional claims be revised, discontinued, or that physicians and patients be notified of off-label promotion. Any compliance action by the FDA may jeopardize patient relationships and reduce our product net revenues.

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If the IR 1250 or the IR 1200 experiences technical issues, we could have reduced demand for the pump resulting in reduced net revenues in a particular quarter or year or increased warranty costs or scrap costs.

The IR 1250 and 1200 pumps are small, complex, densely packaged products that are subject to significant abuse in the field. We began shipping our newest pump, the IR 1250, in February 2005. We expect the sales of the IR 1250 to supplant sales of the IR 1200 domestically, but we expect to continue to sell the IR 1200 internationally. There is limited patient use data for the IR 1250. If the IR 1250/1200 experiences technical issues, such as problems with reliability, reports of actual or adverse events, or manufacturing issues, we could decide to temporarily halt shipments of such product or realize reduced demand for such product, resulting in reduced net revenues in a particular quarter or year.

We face competition from several competitors some of whom have far greater resources, which may make it more difficult for us to achieve significant market penetration.

The market for our products is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. We currently have five principal competitors:

Medtronic MiniMed, a division of Medtronic Inc.;

Roche Disetronic, a division of Roche Diagnostics;

Smiths Medical MD, Inc. (formerly known as Deltec, Inc.), a subsidiary of Smiths Group plc;

Nipro Medical Corporation, a subsidiary of Nipro Corporation; and

Sooil Development Co., Ltd.

Some of our competitors are large, well capitalized companies with significantly greater resources for product development and marketing. Medtronic has the majority share of the insulin pump market in the United States. Roche Disetronic currently has the leading market share of the insulin pump market in Europe. Roche Disetronic is currently prohibited by the FDA from selling its insulin pumps in the United States. We anticipate that Roche Disetronic will reenter the United States insulin pump market in the second quarter of 2005.

At any time, other companies may develop additional competitive products. If we were unable to compete effectively against existing or future competitors, net revenues of our products would decline. Some of our competitors compete by lowering the price of their insulin pumps or ancillary supplies. If these competitors products were to gain acceptance by payors, healthcare professionals, or patients, a downward pressure on prices could result. If prices were to fall, we may not improve our sales growth sufficiently to achieve profitability.

We have approximately $1.2 million of inventory of IR 1000 used pumps as a result of our upgrade program and warranty repair which we expect to sell sometime in the future. Due to rapid product development, this inventory could become obsolete and could result in a write-off of inventory if we cannot sell these used pumps.

We believe that there is a market for refurbished used pumps both in United States and outside the United States. Certain of our competitors have sold refurbished used pumps successfully throughout the world. We have just started selling refurbished used pumps and believe that we have adequately reserved for obsolete inventory. If we are unsuccessful at establishing a sufficiently large market for refurbished used pumps, our inventory reserve may not be adequate.

We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping applicable product or require us to obtain licenses from third parties, to develop non-infringing alternatives, and/or subject us to substantial monetary damages and injunctive relief.

Third parties could, in the future, assert infringement or misappropriation claims against us with respect to our current or future products. Although we perform investigations of the intellectual property of third parties, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Any such infringement or misappropriation claim could result in significant costs, substantial damages, and our inability to manufacture, market, or sell our existing or future products. We could be prohibited from shipping product that is found to infringe. We also could be forced to obtain licenses from third parties or to develop a non-infringing alternative, which could be costly and time-consuming. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest, and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition, and operating results. A court also could enter orders that temporarily, preliminarily, or permanently enjoin us and/or our customers from making, using, selling, offering to sell, or importing our products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

The medical device industry is litigious with respect to enforcement of intellectual property rights. One of our competitors, Medtronic MiniMed, is currently suing another one of our competitors, Smiths Medical MD, Inc., for infringement on certain patents. We have

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reviewed these patents with our patent counsel and believe that we have the right to make, use, sell, and offer to sell our products without infringement liability.

A significant disruption by certain of our vendors could have a material adverse effect on our production output, net revenues, and overall financial performance.

We rely upon certain vendors to supply certain parts for our products on a sole source basis. Our arrangements with these vendors are not on a contractual basis and can be terminated by either party with no advance notice. Although we have identified alternative vendors for these sole source vendors if there is a sudden termination, we may not be able to qualify these vendors in sufficient time without realizing a disruption in production output. Such a disruption could have a material adverse effect on our production output, net revenues, and overall financial performance.

We have a history of net losses and may never achieve or maintain the profitability levels desired by investors.

We have incurred losses every year since our inception in 1996. We incurred losses of $16.7 million in 2004, $17.8 million in 2003, and $19.4 million in 2002. As of December 31, 2004, we had an accumulated deficit of $99.8 million. We will need to achieve the revenues goals we have set for the year 2005, and keep our spending within budget, in order to achieve the income goals we have set forth. We may be unable to do so, and therefore may never achieve the desired income goals. Even if we do achieve the desired level of profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis due to, among other things, competitive pressures and regulatory compliance.

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 Katherine D. Crothall, our President and Chief Executive Officer. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers, and other highly skilled personnel. Competition for senior management personnel, as well as scientists, 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 Ms. Crothall, certain other members of our senior management, scientists, clinicians, or engineers could prevent the implementation and completion of our objectives, including, without limitation, increasing our market share for our existing products, the development and introduction of our products under development, and our revenue goals. The loss of a member of senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement.

Additionally, the sale and after-sale support of an insulin pump is logistically complex, requiring us to maintain an extensive infrastructure of field sales personnel, diabetes educators, customer support, inside sales, 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 the pace of our product development fails to keep up with that of our competitors, our net revenues and future profitability could be adversely affected.

We are currently developing further enhancements to the IR 1250/1200, future generation pumps, and new products such as our ezSet Infusion Set, ezSet Inserter, and continuous glucose sensor. Development of these products requires additional research and development expenditures. Marketing of these products may require FDA and other regulatory clearances or approvals. We may not be successful in developing, manufacturing, or marketing these new products. Furthermore, if our pace of product development fails to keep up with our competitors, our net revenues and future

profitability could be adversely affected.

In our acquisitions of Cygnus and Debiotech technologies, or in future acquisitions, if any, we could encounter difficulties that harm our business.

We have acquired and may acquire, in the future, additional companies, products or technologies that we believe to be complimentary to our business. If we do so, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may be dilutive to existing stockholders, disrupt our ongoing business, distract our management and employees and increase our expenses, which could harm our business. We also cannot be assured that we will realize value from any acquisition that would justify the consideration paid.

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Our plans to achieve our future profitability goals depend upon the successful completion of the development of our ezSet infusion set, the commercial acceptance of this product, and our ability to have this product manufactured at low cost.

Infusion sets are ancillary supplies used in the delivery of insulin to patients using an insulin pump. We currently purchase infusion sets from third party suppliers. Over the last several years, we have been developing our own infusion set called the ezSet infusion set. We believe that we can manufacture this set at a lower cost than the cost at which we currently procure infusion sets from third party suppliers. If we are not successful in completing the development of this product, manufacturing this product at our anticipated costs and acceptable quality, or achieving commercial acceptance of this product, our ability to achieve our future profitability goals may be adversely affected.

Technological breakthroughs in diabetes monitoring, treatment, or prevention could render our products obsolete.

The diabetes treatment market is subject to rapid technological change and product innovation. Our products are based on our proprietary technology, but a number of companies and medical researchers are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs, and other therapeutics for the monitoring, treatment, and/or prevention of insulin-requiring diabetes. FDA approval of a commercially viable continuous glucose monitor or sensor, in particular by one of our competitors that provides real time and accurate data could have a material adverse effect on our net revenues and future profitability. Several of our competitors are in various stages of development of continuous glucose monitors or sensors, and the FDA has approved three of these products. None of these products is labeled for use as a substitute for current finger-stick blood glucose testing. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure, or improve treatment of diabetes. Therefore, our products may be rendered obsolete by technological breakthroughs in diabetes monitoring, treatment, or prevention.

If we are unable to capture the recurring purchases of ancillary supplies by patients using our pumps, we may not be able to adequately implement our growth strategy, resulting in a decrease in our net revenues and limitations on attaining future profitability.

One of our core strategies, in terms of both realizing significant revenue growth and future profitability, is to capture the recurring sales of ancillary supplies to patients using our pumps. If patients stop buying ancillary supplies from us for any number of reasons, including our inability to timely deliver ancillary supplies or more competitive pricing from other suppliers, we may not be able to adequately implement our growth strategy, resulting in a decrease in our net revenues and limitations on attaining future profitability.

Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our patented or proprietary technology and other intellectual property rights, which could substantially impair our ability to compete.

Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, trade secret, copyright and trademark law, and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us.

We may in the future need to assert claims of infringement against third parties to protect our intellectual property. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition, results of operations and cash flows regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not

infringed, invalid, or unenforceable, and could award attorney fees. Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology, or other information that we regard as proprietary. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our patented or proprietary technology and other intellectual property rights, which could substantially impair our ability to compete.

We may experience significant fluctuations in our quarterly results.

The fluctuations in our quarterly results of operations have and will continue to result from numerous factors, including:

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delays in shipping our products due to technical issues;

practices of insurance companies and other third party payors with respect to reimbursement for our products, which tend to result in increased sales of our pumps later in the calendar year after patients deductibles are satisfied;

market acceptance of our products;

timing of regulatory approvals and clearances;

new product introductions;

competition;

our ability to manufacture our products efficiently; 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 operating results 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. For a further discussion of the fluctuations of our operating results, see Management s Discussion and Analysis of Financial Condition and Results of Operations Seasonality and Quarterly Results.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our products. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If our 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 products or failing to adhere to the operating guidelines of our insulin pumps in our user guides 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, could prevent or interfere with our product commercialization efforts, and could reduce product net revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition, reducing our operating results and cash flows.

Failure to secure or retain third party coverage or reduced reimbursement for our products by third party payors could adversely affect our business and operating results.

Substantially all of our pumps and ancillary supplies are paid for by third party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, Medicare, and Medicaid. Healthcare market initiatives in the United States may lead third party payors to decline or reduce reimbursement for our products. Failure to secure or retain third party coverage or reduced reimbursement for our products by third party payors could adversely affect our business and operating results.

We plan to expand further into markets outside the United States, which subjects us to additional business and regulatory risks.

We intend to increase our market share internationally and expect that a material portion of our net revenues and expenses will be derived from operations in foreign countries. Conducting business internationally subjects us to a number of risks and uncertainties including:

fluctuations in foreign currencies;

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unexpected delays or changes in regulatory requirements;

availability of reimbursement within prevailing healthcare payment systems;

delays and expenses associated with tariffs and other trade barriers;

restrictions on and impediments to repatriation of our funds and our distributors ability to make payments to us;

political and economic instability;

difficulties and costs associated with attracting and maintaining third party distributors;

uncertainty in shipping and receiving products and product components;

increased difficulty in collecting accounts receivable and longer accounts receivable cycles in certain foreign countries; and

adverse tax consequences or overlapping tax structures.

We conduct business in a heavily regulated industry and if we fail to comply with these laws and government regulations, we could suffer penalties or be required to make significant changes to our operations.

The healthcare industry is subject to extensive federal, state, and local laws and regulations relating to:

billing for services;

financial relationships with physicians and other referral sources;

inducements and courtesies being given to patients;

quality of medical equipment and services;

confidentiality, maintenance, and security issues associated with medical records and individually identifiable health information;

false claims;

professional licensure; and

labeling products.

These laws and regulations are extremely complex and, in some cases, still evolving. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations.

To the best of our knowledge, we are conforming to all applicable healthcare industry regulations and laws. Regulatory authorities that enforce the various statutes may determine that we are violating federal, state, or local laws and we may need to restructure some of our operations.

If our operations are found to be in violation of any of these federal, state, or local laws and regulations described in this risk factor or the other governmental regulations which govern our activities, we may be subject to the applicable

penalty associated with the violation, including civil and criminal penalties, damages, fines, or curtailment of our operations, which, individually or in the aggregate, would adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

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In addition, healthcare laws and regulations may change significantly in the future. We monitor these developments and will modify our operations from time to time as the regulatory environment changes. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a way that restricts our operations.

We are not aware of any governmental healthcare investigations involving our executives, our managers, or us. Any future healthcare investigations of our executives, our managers, or us could result in significant liabilities or penalties to us, as well as adverse publicity.

All of our operations are conducted at a single location. Any disruption at our facility could increase our expenses.

All of our operations are conducted at a single location. We take precautions to safeguard our facility, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a tornado, 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.

Any disruption in the operation of our proprietary business-management software could interrupt our operations or interfere with our ability to provide service to patients, healthcare providers and payors, which could result in reduced net revenues and adversely affect our operations and financial performance.

We have developed and utilize a proprietary business-management software, ACcessIT, which is critical to our sales, billing, and collections, and customer service functions. Our operations depend upon the proper functioning of ACcessIT. There are no commercial substitutes to this software. This software, as well as any ancillary hardware, is vulnerable to damage or interruption from:

- fire, flood, and other natural disasters;
- power loss, computer systems failures, Internet and telecommunications or data network failure, operator negligence, improper operation by or supervision of employees, physical and electronic loss of data or security breaches, misappropriation, and similar events; and
- computer viruses.

Any disruption in the operation of our propriety business-management software, the loss of employees knowledgeable about such software, or our failure to continue to effectively modify and upgrade such software could interrupt our operations or interfere with our ability to provide service to patients, healthcare providers, and payors, which could result in reduced net revenues and adversely affect our operations and financial performance.

The market price for our common stock may be volatile and could result in a decline in the value of your investment.

The price at which our common stock trades may be volatile. The market price of our common stock is subject to significant fluctuations in response to our operating results, general trends in prospects for the insulin pump industry, announcements by our competitors, analyst recommendations, our ability to meet or exceed analysts or investors expectations, the condition of the financial markets, and other factors. In addition, the stock market in recent years has experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of companies. These fluctuations, as well as general economic and market conditions, may adversely

affect the market price of our common stock notwithstanding our actual operating performance. Significant volatility may lead to securities class action litigation against us. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management s attention and resources. Our insurance to cover claims of this sort may not be adequate.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risks related to our operations result primarily from changes in interest rates. As of December 31, 2004, cash equivalents of $29.7 million were maintained in money market funds of short-term duration. We believe that a 10% change in interest rates would not have a material impact on the results of our operations. The interest rate on our credit facilities is based off the prime rate of our lenders. As of December 31, 2004, we had no amounts outstanding under our credit facilities.

Although approximately 7.2% of our net revenues for the year ended December 31, 2004 were derived from sales outside of the United States and certain of our product components are sourced from suppliers outside of the United States, all of our transactions are invoiced in U.S. dollars. Accordingly, we have no direct exposure to currency exchange risk. However, future fluctuations in the value of the U.S. dollar may affect demand for our products sold in foreign countries and the cost of our foreign-sourced components. As of December 31, 2004, we were not engaged in any foreign currency hedging activities

Item 8. Financial Statements and Supplementary Data

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

No reports on Form 8-K were filed during 2004 or 2003 relating to any disagreements with accountants on accounting and financial disclosures.

Item 9A. Controls and Procedures

(a) Evaluation of disclosure controls and procedures. Our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were designed and functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

(b) Changes in internal controls. There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control over financial reporting that occurred during the fiscal year ended December 31, 2004 which materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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PART III

Item 10. Directors and Executive Officers of the Registrant

Information concerning directors and executive officers, appearing under the captions Governance of the Company , Election of Directors and Other Matters -- Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement to be filed in connection with our Annual Meeting of Stockholders with the Securities and Exchange Commission within 120 days after close of the fiscal year covered by this annual report (the Proxy Statement), are incorporated herein by reference in response to this Item 10.

Edward L. Cahill has served as a member of our board of directors since March 2001. Mr. Cahill also serves as a director of Occupational Health + Rehabilitation Inc. (OTCBB: OHRI) and is a trustee of Johns Hopkins Medicine and Johns Hopkins Health System. Since April 2000, Mr. Cahill has been a Managing Partner at HLM Venture Partners, which invests in emerging healthcare, business services and technology companies. From June 1995 until April 2000, Mr. Cahill was a Founding Partner of Cahill, Warnock & Company (now Camden Partners), a Baltimore private equity firm. Prior to that, Mr. Cahill was a Managing Director of Alex. Brown & Sons, where he headed the firm s Health Care group from 1986 through 1995. Mr. Cahill holds an A.B. from Williams College and a Master of Public and Private Management degree from Yale University.

Graeme Crothall has served as a member of our board of directors since March 2002. Mr. Crothall is founder, President and Chief Executive Office of GCA Services Group, Inc., which provides facilities management services to corporate, industrial, and education clients and has been in business since January 2003. Prior to that, in 1991, Mr. Crothall formed Crothall Services Group, which provided facilities management services to nationwide hospitals, and which he sold to Compass Group PLC in 2001. Mr. Crothall continued to work for Crothall Services Group until December 2002. Mr. Crothall is a graduate of the University of Canterbury, New Zealand, with a postgraduate degree in Mathematics. Mr. Crothall is the husband of Katherine D. Crothall, our President and Chief Executive Officer.

William A. Graham IV has served as a member of our board of directors since December 1999. Since June 1999, Mr. Graham has been Chairman of The Graham Company, a regional insurance agency/brokerage specializing in commercial insurance. From June 1970 to June 1999, Mr. Graham served as President of this family-owned business. Mr. Graham joined the business upon graduation from college, and became sole owner of the company in 1972. Mr. Graham holds a B.S. in Business Administration from Bucknell University, Lewisburg, Pennsylvania.

David Joseph has served as a member of our board of directors since 1996 and is the chairman of our governance and nominating committee. Mr. Joseph is co-founder, director, Chairman, and Chief Executive Officer of Othera Pharmaceuticals Inc., which designs and develops ophthalmic drugs, and was founded in January 2002. He previously served as President, Chief Executive Officer and Chairman of Orthovita, Inc. an orthopedics biomaterials company which he founded in 1993. He retired from Orthovita as Chairman and Director in June 2003. Prior to Orthovita, Mr. Joseph co-founded Surgical Laser Technologies, Inc. in 1985, and served as Chairman and Chief Executive Officer, taking the company public in 1989. Mr. Joseph holds a B.S. from King s College, and a M.B.A. in Healthcare Administration from Xavier University.

John J. McDonough has served as a member of our board of directors since March 2002 and is the chairman of our audit committee. Mr. McDonough co-founded and has been Chairman of McDonough Medical Products Corporation, which manufactures, markets, and supplies medical and dental imaging devices, since June 2001. Mr. McDonough served as Vice Chairman and Chief Executive Officer of Newell Rubbermaid Inc. from January 1998 through December 2000. Prior to that, Mr. McDonough was Chairman and Chief Executive Officer of GENDEX Corporation, which he founded in April 1983, until it merged with DENTSPLY, a manufacturer of dental supplies and equipment for the worldwide dental market, in June 1993. He was Vice Chairman and Chief Executive Officer of DENTSPLY

International Inc. until February 1995, then served as Vice Chairman of DENTSPLY through October 1995. Mr. McDonough is the immediate past Chairman of the International Board of the Juvenile Diabetes Research Foundation. He is currently a member of the Board of the Juvenile Diabetes Research Foundation International and serves on its Executive Committee and special committees of the Board. Mr. McDonough graduated with honors from the University of Notre Dame, and is a certified public accountant.

Thomas Morse has served as a member of our board of directors since March 2001 and is the chairman of our compensation committee. In 1996, Mr. Morse co-founded, and currently serves as principal of Liberty Venture Partners, a venture capital firm that specializes in emerging growth companies in the healthcare and technology industries. Prior to that, Mr. Morse was at Philadelphia Ventures, an early stage venture capital firm. Mr. Morse has received the Certified Financial Analyst designation and holds a B.S. from the U.S. Naval Academy and a M.B.A. from the Wharton School of the University of Pennsylvania.

A. Peter Parsons has served as a member of our board of directors since November 1998. Since January 1988, Mr. Parsons has been a partner at the law firm of Davis Wright Tremaine LLP, specializing in the areas of technology, corporate and securities law, and mergers and acquisitions. Mr. Parsons holds a B.S. in Finance and Accounting from Florida Atlantic University and a J.D. from Duke

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University School of Law and is a former certified public accountant.

Katherine D. Crothall founded Animas Corporation in 1996 and has served as our President, Chief Executive Officer and Chairman of the Board since 1996. From October 1988 to September 1993, Ms. Crothall was President and Chief Executive Officer of Luxar Corporation. Luxar, which she founded in 1988, sold and manufactured CO_2 lasers for cosmetic, oral, surgical, dental, dermatological, and surgical applications. Ms. Crothall also founded and was President of Laakmann Electro-Optics, which manufactured and marketed CO_2 lasers, and was sold to Johnson & Johnson in 1981. Ms. Crothall holds a B.S. in Electrical Engineering from the University of Pennsylvania and a Ph.D. in Electrical Engineering from the University of Southern California.

Richard Baron has served as our Vice President-Finance and Chief Financial Officer since May 2000. From March 1997 to May 2000, Mr. Baron was Vice President-Finance and Chief Financial Officer for Genex Services, a managed care provider for workers compensation and disability. From August 1993 to March 1997, Mr. Baron was Vice President-Finance and Chief Financial Officer for Marsam Pharmaceuticals Inc., a generic manufacturer of injectible anti-infectives. Mr. Baron is a certified public accountant and holds a B.S. in Economics, concentration in Accounting, from the Wharton School of the University of Pennsylvania.

Audrey Finkelstein has served as our Executive Vice President Marketing, Sales and Clinical Affairs since May 2003. From November 1998 to April 2003, Ms. Finkelstein served as our Vice President of Marketing and Clinical Affairs. Prior to this position, Ms. Finkelstein was Director of Clinical Affairs at Luxar Corporation, and subsequently at ESC Medical Systems, which acquired Luxar. Ms. Finkelstein holds a B.S. in Education from Baruch College in New York City.

James McGee has served as our Vice President, Sales since June 2003. From February 1997 to March 2003, Mr. McGee held various positions with Medtronic MiniMed, a division of Medtronic, Inc., a provider of insulin pump therapy, including Vice President of Sales and Marketing (Home Medical Supplies), Director of Managed Care and Vice President of Patient Services. Mr. McGee holds a B.S. in Biology from the University of Central Florida.

Patrick Paul has served as our Vice President, Advanced Technology since November 2004 and prior to that, as Vice-President, Engineering since July 2001. From August 1998 to June 2001, Mr. Paul was the U.S. R&D Director for Siemens Hearing Instruments, Inc. From October 1988 until August 1998, Mr. Paul held several positions with Sulzer-Intermedics Corporation, the Cardiac Rhythm Management division of the Swiss conglomerate Sulzer Ltd. At Sulzer-Intermedics Corporation, Mr. Paul served as Manager of Product Development, Director of Bradycardia Development, and then Director of Advanced Technologies. Mr. Paul holds an Electrical Engineering Degree from the University of Bordeaux in France.

Doug Woodruff has served as our Vice President, Quality and Regulatory Affairs since December 2004. From July 2003 to December 2004, Mr. Woodruff was the Quality Assurance Director from Datascope Corporation, a medical device manufacturer. From April 1999 until July 2003, Mr. Woodruff was Vice President of Quality Affairs and Regulatory Affairs for MedSource Technologies, a contract manufacturer. Mr. Woodruff holds a B.S and a M.S. in Engineering from Washington State University.

Executive Officers

Our executive officers are elected by, and serve at the discretion of, our board of directors. Other than Graeme Crothall, a director, who is the husband of Katherine D. Crothall, our President, Chief Executive Officer, and Chairman of the Board, there are no family relationships among our directors and executive officers.

Code of Business Conduct and Ethics

We have a Code of Business Conduct and Ethics which can be viewed on our by our website at http://www.animascorp.com (under Investor Relations and Governance Documents). We require all employees to adhere to the Code in addressing the legal and ethical issues encountered in conducting their work. The Code of Business Conduct and Ethics requires that our employees avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner, and otherwise act with integrity and in our best interest. The Code of Business Conduct and Ethics is intended to comply with Item 406 of the SEC s Regulation S-K and the rules of NASDAQ.

The Code of Business Conduct and Ethics includes procedures for reporting violations of the Code, which are applicable to all employees. The Sarbanes-Oxley Act of 2002 requires companies to have procedures to receive, retain and treat complaints received regarding accounting, internal accounting controls or auditing matters and to allow for the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters.

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The Code of Business Conduct and Ethics also includes these required procedures.

Any waiver or amendment of the Code of Business Conduct and Ethics for designated senior officers, including our Chief Executive Officer and Chief Financial Officer, will be disclosed promptly on our Internet website.

Copies of the Code of Business Conduct and Ethics appear on our website and are also available upon request by any stockholder addressed to our Chief Financial Officer, 200 Lawrence Drive, West Chester, PA 19380.

Item 11. Executive Compensation

The information contained in the sections titled Executive Officers and Executive Compensation and Compensation of Directors in the Proxy Statement is incorporated herein by reference in response to this Item 11.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information contained in the section titled Securities Ownership of Certain Beneficial Owners and Management in the Proxy Statement is incorporated herein by reference in response to this Item 12.

Item 13. Certain Relationships and Related Transactions

The information contained in the section titled Certain Relationships and Related Transactions in the Proxy Statement is incorporated herein by reference in response to this Item 13.

Item 14. Principal Accountant Fees and Services

The information contained in the section titled Fees to Independent Public Accountants in the Proxy Statement is incorporated herein by reference in response to this Item 14.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report:

1. Financial Statements

The financial statements as set forth under Item 8 of this report on Form 10-K are incorporated herein.

2. Financial Statement Schedules

All financial statement schedules have been omitted here because they are not applicable, not required or the information is shown in the financial statements or related notes.

3. Exhibits

EXHIBIT NUMBER	DESCRIPTION
3.1	Amended and Restated Certificate of Incorporation of Animas Corporation (1)
3.2	Amended and Restated Bylaws of Animas Corporation (1)
10.1	Silicon Valley Bank Loan and Security Agreement dated November 4, 2002 by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.2	Loan Modification Agreement dated November 7, 2003 by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.2 to the Company s

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EXHIBIT NUMBER	DESCRIPTION
	Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.3	Silicon Valley Bank Loan and Security Agreement dated November 7, 2003, by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.4	Negative Pledge Agreement dated November 4, 2002, by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.4 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.5	Negative Pledge Agreement dated November 7, 2003, by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.5 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.6	Equipment Term Note dated as of November 4, 2002 from Animas Corporation to Silicon Valley Bank (incorporated by reference to Exhibit 10.6 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.7*	1996 Incentive Stock Plan (incorporated by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.8*	1998 Equity Compensation Plan (incorporated by reference to Exhibit 10.8 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.9*	2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)
10.10*	2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)
10.11	Agreement of Lease dated June 24, 2003 by and between Berwind Property Group, Ltd. and Animas Corporation (incorporated by reference to Exhibit 10.12 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.12*	Amended and Restated Employment Agreement by and between Animas Corporation and Katherine D. Crothall dated February 20, 2004 (incorporated by reference to Exhibit 10.13 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.13*	Employment Agreement by and between Animas Corporation and Richard Baron dated February 20, 2004 (incorporated by reference to Exhibit 10.14 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.14*	

Form of Change of Control Agreement between Animas Corporation and certain executive officers (incorporated by reference to Exhibit 10.15 to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)

10.15 Amended and Restated Registration Rights Agreement dated as of October 11, 2001 by and among Animas Corporation and certain holders of Preferred Stock in Animas Corporation (incorporated by reference to Exhibit 10.16 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)

10.15(A) First Amendment to Amended and Restated Registration Rights Agreement dated as of May 13, 2002 by and among Animas Corporation and certain holders of Preferred Stock in Animas Corporation (incorporated by reference to Exhibit 10.16(A) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)

10.15(B) Second Amendment to Amended and Restated Registration Rights Agreement dated as of January 21, 2003 by and among Animas Corporation and certain holders of Preferred Stock in Animas Corporation (incorporated by reference to Exhibit 10.16(B) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)

10.15(C) Third Amendment to Amended and Restated Registration Rights Agreement dated as of November 18, 2003 by and among Animas Corporation and certain holders of Preferred Stock in Animas Corporation (incorporated by reference to Exhibit 10.16(C) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)

10.15(D) Fourth Amendment to Amended and Restated Registration Rights Agreement dated as of March 24, 2004 by and among Animas Corporation and certain holders of Preferred Stock in Animas Corporation (incorporated by reference to Exhibit 10.16(D) to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)

10.16 Investor Rights Agreement dated as of January 28, 2000, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17 to the Company s

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EXHIBIT NUMBER	DESCRIPTION
	Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.16(A)	First Amendment to Investor Rights Agreement dated as of January 22, 2001, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17(A) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.16(B)	Second Amendment to Investor Rights Agreement dated as of October 11, 2001, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17(B) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.16(C)	Third Amendment to Investor Rights Agreement dated as of May 13, 2002, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17(C) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.16(D)	Fourth Amendment to Investor Rights Agreement dated as of January 21, 2003, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17(D) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.16(E)	Fifth Amendment to Investor Rights Agreement dated as of November 18, 2003, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17(E) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.16(F)	Sixth Amendment to Investor Rights Agreement dated as of March 24, 2004 by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.17(F) to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)
10.17	Amended and Restated Stockholders Agreement dated as of October 11, 2001, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.18 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.17(A)	First Amendment to Amended and Restated Stockholders Agreement dated as of May 13, 2002, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.18(A) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.17(B)	Second Amendment to Amended and Restated Stockholders Agreement dated as of January 21, 2003, by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.18(B) to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)

10.17(C)	Third Amendment to Amended and Restated Stockholders Agreement dated as of March 24, 2004 by and among Animas Corporation and certain stockholders of Animas Corporation (incorporated by reference to Exhibit 10.18(C) to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)
10.18	Second Loan Modification to Silicon Valley Bank Loan and Security Agreement dated November 4, 2002, by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank dated February 19, 2004 (incorporated by reference to Exhibit 10.19 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.19	First Loan Modification to Silicon Valley Bank Loan and Security Agreement dated November 7, 2003, by and among Animas Corporation, Animas Diabetes Care, LLC and Silicon Valley Bank dated February 19, 2004 (incorporated by reference to Exhibit 10.20 to the Company s Registration Statement on Form S-1, Registration No. 333-113008 filed February 23, 2004)
10.20	Silicon Valley Bank Irrevocable Standby Letter of Credit dated August 21, 2003, for the benefit of Lawrence Road Investors, L.P. (incorporated by reference to Exhibit 10.21 to the Company s Registration Statement on Form S-1/A, Registration No. 333-113008 filed April 2, 2004)
10.21*	2004 Equity Incentive Plan Incentive Stock Option Grant (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004)
10.22*	2004 Equity Incentive Plan Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004)
10.23*	Summary of Director and Executive Compensation (1)

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EXHIBIT NUMBER	DESCRIPTION
10.24	License, Joint Development and Manufacturing Assistance Agreement (2)
10.25	Micro-Needle License, Joint Development and Manufacturing Assistance Agreement (2)
10.26	Asset Purchase Agreement dated December 16, 2004 by and between Cygnus, Inc., Animas Corporation and Animas Technologies LLC (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed March 24, 2005)
21	Subsidiaries of Animas Corporation (1)
23.1	Consent of KPMG LLP (1)
31.1	Certification by President and Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a) (1)
31.2	Certification by Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a) (1)
32.1	Certification Furnished Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (1)

(1) Filed herewith

(2) Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to a request for confidential treatment that has been filed with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

* Management contracts and compensatory plans and arrangements required to be filed as exhibits pursuant to Item 15(c) of this report.

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Pursuant to the requirements 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.

/s/ Richard Baron

Richard Baron
Vice President Finance and Chief Financial Officer

DATE: March 31, 2005

Animas Corporation
(Registrant)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 31, 2005 by the following persons on behalf of the registrant and in the capacities indicated.

Signature and Title	Signature and Title
/s/ Katherine D. Crothall	*/s/ David Joseph*
Katherine D. Crothall President, Chief Executive Officer and Director	David Joseph Director
/s/ Edward Cahill	*/s/ John J. McDonough*
Edward Cahill Director	John J. McDonough Director
/s/ Graeme Crothall	*/s/ Thomas Morse*
Graeme Crothall Director	Thomas Morse Director
/s/ William A. Graham IV	*/s/ A. Peter Parsons*
William A. Graham IV Director	A. Peter Parsons Director

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Animas Corporation:

We have audited the accompanying consolidated balance sheets of Animas Corporation and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Animas Corporation and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 25, 2005

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ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2004	December 31, 2003
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 30,867	$ 384
Accounts receivable, net of allowance for doubtful accounts of $1,702 in 2004 and $1,285 in 2003	22,382	13,178
Inventories	10,924	3,335
Cost associated with deferred revenue		1,025
Prepaid expenses and other current assets	1,378	575
Total current assets	65,551	18,497
Property and equipment, net	6,780	3,899
Deposits and other assets	3,654	297
Restricted cash		550
Total assets	$ 75,985	$ 23,243
Liabilities and Stockholders Equity		
Current liabilities:		
Lines of credit	$	$ 2,657
Current portion of long-term debt	398	462
Accounts payable	4,430	2,752
Accrued expenses	4,077	8,462
Total current liabilities	8,905	14,333
Other liabilities	1,820	1,140
Long-term debt	254	467
Total liabilities	10,979	15,940

Commitments and contingencies (Note 10)		
Stockholders equity:		
Series A, B, and C Preferred stock, $0.01 par value; authorized 10,000,000 shares in 2004 and 8,353,200 shares in 2003; none issued and outstanding in 2004 and 7,097,724 in 2003		71
Common stock, $0.01 par value; authorized 100,000,000 shares in 2004 and 24,000,000 shares in 2003; issued and outstanding 20,022,765 shares in 2004 and 3,987,282 in 2003	200	40
Additional paid-in capital	164,784	90,544
Deferred compensation	(142)	(178)
Accumulated deficit	(99,836)	(83,174)
Total stockholders equity	65,006	7,303
Total liabilities and stockholders equity	$ 75,985	$ 23,243

The accompanying notes are an integral part of the consolidated financial statements.

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ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Statements of Operations

	Years Ended December 31,		
	2004	2003	2002
	(in thousands, except share and per share data)		
Net revenues	$ 67,926	$ 34,120	$ 23,598
Operating expenses:			
Cost of products sold	26,986	16,759	12,384
Research and development expenses	6,301	5,173	3,921
Selling, general and administrative expenses	36,793	29,800	26,741
Purchased in-process research and development	14,521		
Total operating expenses	84,601	51,732	43,046
Loss from operations	(16,675)	(17,612)	(19,448)
Interest income	361	22	158
Interest expense	(348)	(214)	(84)
Net loss	(16,662)	(17,804)	(19,374)
Deemed dividend - beneficial conversion feature of preferred stock (Note 9)		(7,878)	
Net loss attributable to common stockholders	$ (16,662)	$ (25,682)	$ (19,374)
Basic and diluted net loss attributable to common stockholders per share	$ (1.23)	$ (6.64)	$ (5.02)
Weighted average shares - basic and diluted	13,521,644	3,869,844	3,861,614

The accompanying notes are an integral part of the consolidated financial statements.

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ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Statements of Stockholders Equity

Years Ended December 31, 2004, 2003 and 2002

	Preferred stock		Common stock		Additional paid-in	Deferred	Accumulated	Total stockholders
	Shares	Amount	Shares	Amount	capital	compensation	deficit	equity
	(in thousands, except share and per share data)							
Balance, January 1, 2002	5,167,555	$ 52	3,856,649	$ 39	$ 57,373	$	$ (38,118)	$ 19,346
Sale of preferred stock at $12.50 per share, net of offering costs	581,545	6			7,229			7,235
Issuance of stock options for services rendered					184			184
Exercise of stock options to purchase common stock			9,333		44			44
Deferred compensation associated with stock grants					80	(80)		
Amortization of deferred compensation						27		27
Net loss							(19,374)	(19,374)
Balance, December 31, 2002	5,749,100	58	3,865,982	39	64,910	(53)	(57,492)	7,462
Sale of preferred stock at $12.50 per share, net of offering costs	1,348,624	13			16,686			16,699
Issuance of stock options for services rendered					591			591
Exercise of stock options to purchase common stock			121,300	1	314			315
Deferred compensation					165	(165)		

associated with stock grants								
Amortization of deferred compensation						40		40
Net loss							(25,682)	(25,682)
Deemed dividend (Note 9)					7,878			7,878
Balance, December 31, 2003	7,097,724	71	3,987,282	40	90,544	(178)	(83,174)	7,303
Exercise of stock warrants to purchase preferred stock	55,084	1			406			407
Conversion of preferred stock into common stock	(7,152,808)	(72)	9,522,604	95	(23)			
Sale of common stock at $15.00 per share, net of offering costs			4,887,500	49	65,696			65,745
Cashless exchange of warrants			637,378	6	(6)			
Exercise of stock options and warrants to purchase common stock			581,001	6	2,289			2,295
Issuance of stock as consideration for acquisition			400,000	4	5,776			5,780
Deferred compensation associated with stock grants			7,000		102	(76)		26
Amortization of deferred compensation						112		112
Net loss							(16,662)	(16,662)
Balance, December 31, 2004		$	20,022,765	$ 200	$ 164,784	$ (142)	$ (99,836)	$ 65,006

The accompanying notes are an integral part of the consolidated financial statements.

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ANIMAS CORPORATION AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2004	2003	2002
		(in thousands)	
Cash flows from operating activities:			
Net loss	$ (16,662)	$ (17,804)	$ (19,374)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,163	1,679	1,180
Non-cash compensation and interest expense	138	631	211
Write-off of in-process research and development	14,521		
Bad debt expense	1,256	889	316
Other	12		(20)
Changes in net assets and liabilities:			
Accounts receivable, net	(10,460)	(7,001)	(4,573)
Inventories	(7,589)	(611)	(1,537)
Cost associated with deferred revenue	1,025	(1,025)	
Prepaid expenses and other current assets	(803)	(222)	(46)
Deposits and other assets	143	(188)	(26)
Restricted cash	550	(550)	
Accounts payable	1,678	110	1,456
Accrued expenses and other liabilities	(3,705)	5,926	752
Net cash used in operating activities	(17,733)	(18,166)	(21,661)
Cash flows from investing activities:			
Purchases of property and equipment	(4,779)	(1,524)	(1,984)
Payment for acquisition	(12,241)		
Net cash used in investing activities	(17,020)	(1,524)	(1,984)
Cash flows from financing activities:			
Proceeds from lines of credit	12,102	3,885	573
Repayments on lines of credit	(14,759)	(1,478)	(323)
Proceeds from issuance of common stock, net of offering costs	68,040	315	44
Proceeds from long-term debt			1,000
Repayments on long-term debt	(554)	(481)	(357)
Proceeds from sale of preferred stock	407	16,699	7,235

Net cash provided by financing activities	65,236	18,940	8,172
Net increase (decrease) in cash and cash equivalents	30,483	(750)	(15,473)
Cash and cash equivalents at beginning of year	384	1,134	16,607
Cash and cash equivalents at end of year	$ 30,867	$ 384	$ 1,134

The accompanying notes are an integral part of the consolidated financial statements.

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ANIMAS CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share data)

(1) Organization and Description of Business

Animas Corporation (the Company) manufactures and distributes insulin pumps as well as ancillary pump supplies required for the use of the pump. The Company, a Delaware corporation founded in 1996, is located in West Chester, Pennsylvania. The Company received clearance from the Food and Drug Administration (the FDA) for its first insulin pump in February 2000 and began shipping this product in July 2000. The Company received clearance for its third-generation pump, the IR 1200, in October 2003 and began shipping it in April 2004. In December 2004, the Company received clearance for its newest pump, the IR 1250, and began shipping it in February 2005. In the United States, the Company generally markets its products through both a direct sales force and distributors. All of the Company s operations are located in the United States. Although most of the Company s sales of product to patients occur in the United States, it has contracted with independent distributors to sell products in Australia, Austria, Canada, the Czech Republic, France, Finland, Greece, Germany, Hungary, the Republic of Ireland, Israel, Italy, New Zealand, Spain, Sweden and the United Kingdom. The Company is also developing an implantable glucose sensor for people with insulin-requiring diabetes.

In May 2004, the Company completed its initial public offering (IPO) in which it sold 4,887,500 shares of its common stock at $15.00 per share. In connection with the offering, the Company paid $5,132 in underwriting discounts and commissions and incurred $2,435 in other expenses. Net proceeds to the Company were $65,745. As of the closing date of the offering, all of the convertible preferred stock previously outstanding was converted into 9,522,604 shares of common stock.

(2) Summary of Significant Accounting Policies

Principles of Consolidation. The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents. The Company considers all highly liquid debt instruments with an original maturity of three months or less when purchased to be a cash equivalent. Cash and cash equivalents include money market funds and various deposit accounts.

Accounts Receivable Allowance for Doubtful Accounts. Accounts receivable consist of amounts due from third party payors (governmental and non-governmental), distributors, and patients. In estimating the collectability of our accounts receivable, the Company analyzes historical bad debts, payor and patient concentrations, payor and patient credit-worthiness, and current economic trends. These allowances are recorded in the period when the revenue is recorded. Allowances are adjusted currently for any changes in estimated collections.

Accounts receivable are net of allowances for doubtful accounts of $1,702 and $1,285 at December 31, 2004 and December 31, 2003, respectively. Bad debt expense was $1,256, $889, and $316 for the years ended December 31, 2004, 2003, and 2002, respectively. The related write-offs of accounts receivable were $839, $337, and $33 for these periods, respectively.

Inventories. Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Cost for pumps includes material, labor and manufacturing overhead. Ancillary supplies

inventory and raw materials inventory include material costs only.

Property and Equipment. Property and equipment are carried at cost less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets for financial reporting purposes. The estimated useful lives used for financial reporting purposes are as follows:

Laboratory equipment	5 years
Computer equipment	3 years
Manufacturing equipment	5 years
Leasehold improvements	10 years
Furniture and equipment	3 to 7 years
Demo insulin infusion pumps	2 years

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Impairment of Long-lived Assets. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset might not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset s carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised values, depending on the asset.

Product Warranties. The Company provides a four-year warranty on its insulin pumps. Warranty expense is recorded in the period that product shipment occurs. The expense is based on historical experience and projected trends of warranty claims and the estimated cost to settle the claims. At December 31, 2004 and December 31, 2003, accrued product warranties totaled $1,349 and $1,734, respectively, and are classified as a current liability in accrued expenses ($350 and $608, respectively) and as a long-term liability (see Note 8) in other liabilities ($999 and $1,126, respectively) in the accompanying consolidated balance sheets. Given the four-year warranty period of the Company s insulin pumps, the portion of the warranty accrual classified as long-term represents the Company s estimate of costs to settle warranty claims to be incurred in excess of one year from the balance sheet date.

A tabular reconciliation of the changes in the Company s product warranty liability is as follows:

	Year Ended December 31,		
	2004	**2003**	**2002**
Balance at beginning of period	$ 1,734	$ 1,775	$ 1,604
Warranty expense	2,814	820	1,160
Warranty claims settled	(3,199)	(861)	(989)
Balance at end of period	$ 1,349	$ 1,734	$ 1,775

Comprehensive Loss. Comprehensive loss represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. No separate statement of comprehensive loss has been presented because comprehensive loss was equal to net loss in each of the years ended December 31, 2004, 2003 and 2002.

Revenue Recognition. Revenues are generated primarily from the sale of insulin pumps and ancillary supplies. Customers do not have any right of return or any right to cancel or terminate the sale once the pumps or ancillary supplies are shipped. Pump and ancillary supplies net revenues are recognized upon shipment in accordance with Staff Accounting Bulletin No. 104 (SAB 104). In accordance with EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, (EITF 00-21) in instances where the Company provides pump operation training, the Company defers the fair value of the training until it has been delivered. The Company bases the fair value of the training on the historical amount the Company has paid to independent service providers for training patients on the operation of the pump. Though the insulin pump has standalone value, there is no objective evidence as to the pump s fair value since the Company is reimbursed the same amount with or without training. As a result, the residual method under EITF 00-21 is utilized. The Company defers revenues associated with training until it has been delivered.

During the year ended December 31, 2004 approximately 82%, of the Company s products were sold directly to patients. The Company bills these patients directly or bills their healthcare payors. Levels of reimbursements from third party payors vary depending upon the specific benefits provided under each patient s coverage. At the time of sale, the Company records revenue net of a contractual allowance, which represents the difference between the established billing rate and third party payor payments.

As noted above, in October 2003, the Company received FDA clearance for its IR 1200 pump. The Company began shipping the IR 1200 in April 2004. During the period of November 1, 2003 to March 31, 2004, the Company initiated an upgrade program in which the Company offered to each new patient purchasing an IR 1000 pump the option to upgrade to the IR 1200 pump at no additional charge. As required by SAB 104, the Company deferred the recognition of net revenues on all pump shipments with an upgrade obligation. As of September 30, 2004, the Company had completed the upgrade program. As a result of this program, the Company s net revenues for the second and third quarter of 2004 were increased by the recognition of revenues deferred from previous quarters, as the Company shipped upgraded pumps or patients declined the upgrade.

Revenues from products sold directly to domestic and international distributors are recognized upon shipment, and are approximately 18% of the Company s products during the year ended December 31, 2004. Distributors have no right of return. The Company has no post-shipment obligations to its distributors.

Shipping and Handling of Products. Amounts billed to customers for shipping and handling of products are included in net revenues.

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Costs incurred related to shipping and handling of products are included in cost of products sold.

Research and Development. Research and development costs are charged to expense as incurred.

Advertising Costs. Advertising costs, included in selling, general and administrative expenses, are charged to expense as incurred. Advertising expenses in 2004, 2003, and 2002 were $81, $98, and $111, respectively.

Income Taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Deferred tax assets and liabilities are measured at the balance sheet date using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period such tax rate changes are enacted.

Stock-Based Compensation. In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. This standard amends the transition and disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation. As permitted by SFAS No. 148, the Company applies the intrinsic value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations to account for its stock options. Under this method, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. As allowed by SFAS No. 148, the Company has elected to continue to apply the intrinsic value-based method of accounting described above, and has adopted only the disclosure requirements of SFAS No. 148.

Had the Company determined compensation cost for options granted during the years ended December 31, 2004, 2003 and 2002, based on the fair value method, at the grant date under SFAS No. 148, the Company s net loss and net loss per share would have been reported as follows:

	Years Ended December 31,		
	2004	**2003**	**2002**
Net loss attributable to common stockholders, as reported	$ (16,662)	$ (25,682)	$ (19,374)
Add Non-cash employee compensation, as reported	33	501	159
Deduct Total stock-based employee compensation expense determined under fair value-based method	(907)	(385)	(743)
Pro forma net loss attributable to common stockholders	$ (17,536)	$ (25,566)	$ (19,958)
Loss attributable to common stockholders per share:			
Basic and Diluted, as reported	$ (1.23)	$ (6.64)	$ (5.02)
Basic and Diluted, pro forma	$ (1.30)	$ (6.61)	$ (5.17)

The weighted average fair value of the options granted during the years ended December 31, 2004, 2003, and 2002 were $7.20, $1.69, and $1.88, respectively. The fair value of each option is estimated on the date of grant using the

Black-Scholes option-pricing model. The weighted average assumptions used are as follows:

	Years Ended December 31,		
	2004	**2003**	**2002**
Risk-free interest rate	3.46%	2.97%	4.31%
Expected life (in years)	4	5	5
Dividend yield			
Expected volatility	54.20%	%	%

Net Loss per Common Share. Net loss per common share is computed in accordance with SFAS No. 128, Earnings per Share. Under the provisions of SFAS No. 128, basic net loss per share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period.

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Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares and common equivalent shares then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, shares issuable upon the exercise of stock options and warrants and the conversion of preferred stock upon the exercise of warrants. For the three years ended December 31, 2004, Diluted EPS is identical to Basic EPS as the Company is in a net loss position and the common equivalent shares are considered anti-dilutive. As of December 31, 2004, common equivalents consisted of 2,504,492 common stock options and 148,140 common warrants (see Note 9).

Concentration of Credit Risks. The Company s financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Substantially all of our cash and cash equivalents are maintained at major financial institutions in the United States. Deposits at these institutions may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on deposits of cash and cash equivalents.

Accounts receivable consist of amounts due from third party payors (governmental and non-governmental), distributors, and patients. The Company routinely assesses the financial strength of its customers and, generally requires no collateral from its customers. Credit losses have been minimal to date. No single customer accounted for 10% or more of the Company s 2004, 2003 or 2002 net revenues. No customer accounted for more than 10% of total accounts receivable at December 31, 2004 or 2003.

Use of Estimates. The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect 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 revenues and expenses during the reporting period. Some of the more significant estimates include the allowance for doubtful accounts, contractual allowances, inventory obsolescence, and the warranty accrual. Actual amounts could differ from those estimates.

Reclassifications. Certain amounts in the prior year have been reclassified to conform to the current year presentation.

New Accounting Pronouncements. In November 2004, the FASB issued SFAS No. 151 (SFAS 151), Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material should be recognized as current period charges and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. SFAS 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Early adoption is permitted for inventory costs incurred during fiscal years beginning after the date SFAS 151 was issued. SFAS 151 should be applied prospectively. The Company does not expect the adoption of this standard to have a material impact on the consolidated financial position, results of operations and cash flows.

In December 2004, the FASB issued SFAS No. 123(R) (SFAS 123 (R) , Share-Based Payment. SFAS 123(R) revises SFAS 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. SFAS 123(R) will require compensation costs related to share-based payment transactions to be recognized in the financial statements (with limited exceptions). The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. This statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The full impact of adoption of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure

of pro forma net loss and loss per share in Note 2 of the notes to the consolidated financial statements. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company is unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

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(3) Inventories

Inventories consist of the following as of:

	December 31,	
	2004	2003
Raw materials	$ 2,225	$ 1,064
Work in process	5,367	423
Finished goods	3,914	1,848
Less reserve for excess and obsolete inventory	(582)	
	$ 10,924	$ 3,335

(4) Property and Equipment

Property and equipment consist of the following as of:

	December 31,	
	2004	2003
Laboratory equipment	$ 332	$ 281
Computer equipment	2,944	2,272
Manufacturing equipment	3,724	2,750
Leasehold improvements	1,661	727
Furniture and equipment	1,510	1,071
Demo insulin infusion pumps	1,024	
Construction in progress	993	775
	12,188	7,876
Less accumulated depreciation and amortization	(5,408)	(3,977)
	$ 6,780	$ 3,899

Depreciation and amortization expense was $2,163, $1,679 and $1,180 for the years ended December 31, 2004, 2003 and 2002, respectively.

Management has conducted a review of its accounting for the lease of its corporate headquarters, which was entered into in June 2003. The Company did not account for a tenant improvement allowance provided by the landlord on the consolidated balance sheets or on the consolidated statements of cash flows. Management determined that the appropriate accounting under generally accepted accounting principles requires that the allowance be recorded as a deferred rent liability on the consolidated balance sheets and as a component of operating activities on the consolidated cash flow statements. As a result, the Company recorded a leasehold improvement of approximately $909,000 relating to a tenant allowance and a corresponding deferred rent liability at December 31, 2004. The deferred rent liability will be amortized over the lease term as a reduction of rent expense and the addition to leasehold improvements will be amortized over the useful life of the improvement. The cash flow statement for the year ended December 31, 2004 has also been corrected to reflect the tenant allowance as both a cash flow from operations and an

investing activity. The Company has corrected the lease accounting as of December 31, 2004 as management has determined that the amounts are immaterial to financial statements of prior periods.

(5) Deposits and Other Assets

Deposits and other assets consist of the following at:

	December 31,	
	2004	**2003**
Asset associated with acquired technology (see Note 11)	$ 3,500	$
Other assets	154	297
	$ 3,654	$ 297

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(6) Accrued Expenses

Accrued expenses consist of the following at:

	December 31,	
	2004	2003
Salaries and related expenses	$ 1,971	$ 1,963
Other accrued expenses	1,184	712
Deferred revenue	572	5,179
Current portion of warranty accrual (Note 2)	350	608
	$ 4,077	$ 8,462

(7) Lines of Credit and Long-term Debt

The Company had a $250 line of credit facility with a bank that bore interest at 1.50% above the bank s prime rate. The line of credit expired in December 2004. At December 31, 2003, $250 was outstanding. An officer of the Company personally guaranteed the $250 line of credit in 2003.

During 2002, the Company entered into a $3,000 line of credit with a second bank. The line bore interest at 1.00% above the bank s prime rate. In November 2003, the Company replaced the line of credit with a $6,000 line of credit with the same bank. The line of credit availability is based upon eligible accounts receivable and inventory. The line bears interest at 1.75% above the bank s prime rate (7.00% at December 31, 2004). The line of credit expires on May 5, 2005. Borrowings are secured by a pledge of substantially all of the Company s assets. No amounts were outstanding at December 31, 2004 and $2,407 was outstanding at December 31, 2003. The line of credit is used as security for a letter of credit (see Note 10). The weighted-average interest rate was 5.75% and 5.31% during the year ended December 31, 2004 and December 31, 2003, respectively.

Long-term debt consists of the following as of:

	December 31,	
	2004	2003
Note payable to bank due November 4, 2005, in monthly installments of $28 plus interest at 1.5% above the prime rate, secured by certain assets of the Company	$ 238	$ 614
Capital lease obligations (see Note 10)	414	315
	652	929
Less current portion of long-term debt	(398)	(462)
	$ 254	$ 467

The agreement related to the $6,000 line of credit and note payable to bank contains a covenant that requires the Company to maintain a minimum net worth throughout the term of the borrowings. The covenant was modified as a result of the Company deferring certain revenues under SAB 104 (see Note 2). As of December 31, 2004, the Company was in compliance with this covenant.

Maturities of long-term debt are as follows:

2005	$ 398
2006	118
2007	80
2008	50
2009	6
	$ 652

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(8) Other Liabilities

Other liabilities consist of the following at:

	December 31, 2004	2003
Warranty reserve (see Note 2)	$ 999	$ 1,126
Deferred rent	821	14
	$ 1,820	$ 1,140

(9) Stockholders Equity

Preferred Stock. During the first quarter of 2000, the Company sold 1,853,200 shares of Series A Convertible Preferred Stock (Series A) at $6.25 per share, raising total proceeds of $11,077, net of offering costs. In 2004, each share of Series A was converted into the Company s common stock, at a conversion rate of 1.333 shares of common stock for each share of Series A.

In January and February 2001, the Company sold 1,500,000 shares of Series B Convertible Preferred Stock (Series B) at $10.00 per share, raising total proceeds of $14,591, net of offering costs. In 2004, each share of Series B was convertible into the Company s common stock at a conversion rate of 1.333 shares of common stock for each share of Series B.

During the fourth quarter of 2001, the Company sold 1,814,355 shares of Series C Convertible Preferred Stock (Series C) at $12.50 per share, raising total proceeds of $22,617, net of offering costs. In addition, from January to June 2002, the Company sold 581,545 shares of Series C at $12.50 per share, raising total proceeds of $7,235, net of offering costs. In 2004, each share of Series C was converted into the Company s common stock at a conversion rate of 1.333 shares of common stock for each share of Series C.

From January to April 2003, the Company sold 948,624 units at a price of $12.50 per unit for gross proceeds of $11,858. In November 2003, the Company sold 400,000 units at a price of $12.50 per unit for gross proceeds of $5,000. Each unit consisted of one share of Series C and one 10 year warrant to purchase 0.9 shares of Series C exercisable at $12.50 per whole share (Series C Unit).

For each Series C Unit closing in 2003, the proceeds were allocated to the Series C and warrants based on the relative values of each instrument. In valuing the warrants issued from January to April, the underlying value of the common stock was based upon the most recent sale of Series C and the fair value of the warrants issued in November was based upon the mid-point of the estimated initial public offering filing range. Accordingly, approximately $6,795 of the January to April 2003 proceeds was allocated to the Series C and $5,063 of the proceeds was allocated to the warrants. Similarly, $2,815 of the November 2003 proceeds was allocated to the Series C and $2,185 was allocated to the warrants. In addition, in accordance with EITF Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments (EITF No. 00-27), the issuance costs were not offset against the proceeds in calculating the intrinsic value of the conversion option but were considered in the calculation of the amount shown on the consolidated balance sheet. After considering the allocation of the proceeds based on the relative fair values, it was determined that the Series C had a beneficial conversion feature (BCF) in accordance with EITF No. 98-5 and EITF No. 00-27. Accordingly, a BCF adjustment of $5,063 was recorded with respect to the Series C in the January to April closing. The value of the BCF was recorded in a manner similar to a dividend, and since the Series C had no maturity

date and was convertible at the date of issuance, the BCF was charged to the statement of operations. Additionally, the Company recorded a similar deemed dividend during the fourth quarter of 2003, of $2,815 for the value of the BCF with respect to the Series C sold at the November 2003 closing. The deemed dividend on the November 2003 closing was limited since the value of the BCF was limited to the amount of the proceeds allocated to the Series C.

The Company s Series A, B, and C automatically converted into 9,522,604 shares of common stock as a result of the IPO in May 2004 (see Note 1).

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As part of the aforementioned Preferred Stock transactions the following purchases were made by related parties or entities affiliated with such related parties:

	Series A Preferred	Series B Preferred	Series C Preferred	Series C Warrants
Directors and officers	544,550	147,598	1,106,568	342,269
Affiliates of directors and officers	48,000	303,800	449,929	78,956

Stock Options. The Company currently has three stock option plans, the 2004 Equity Incentive Plan (2004 Plan), the Animas Corporation 1998 Equity Compensation Plan (1998 Plan) and the Animas Corporation 1996 Incentive Stock Plan (1996 Plan). Under the 2004 Plan, options and restricted stock can be granted up to a maximum of 6,500,000 shares. As of December 31, 2004, there were 6,113,276 options available for grant under the 2004 Plan. Under the 1998 Plan, options and restricted stock can be granted up to a maximum of 2,866,667 shares. As of December 31, 2004, there were 1,977,733 options outstanding under the 1998 Plan and no additional grants will be made. Under the 1996 Plan, options, stock appreciation rights, or other stock awards, as defined, to purchase 400,000 shares of common stock could have been granted for officers, directors, employees, and consultants. The Company granted 397,760 options under the 1996 Plan. As of December 31, 2004, there were 140,035 options outstanding under the 1996 Plan and no additional grants will be made. The options under each plan expire ten years from the date of grant and typically vest over three to five years. The plans are administered by a committee of the board of directors that determines the type, price, and other terms of all grants under each plan. Certain options granted to executive officers are subject to an accelerated vesting provision (see Note 10).

Information relative to the Company s stock options is as follows:

	Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share
Balance as of January 1, 2002	2,126,527	$ 0.19-9.38	$ 5.03
Granted	580,733	9.38	9.38
Exercised	(9,333)	4.69	4.69
Terminated	(121,067)	4.69-9.38	6.11
Balance as of December 31, 2002	2,576,860	0.19-9.38	5.91
Granted	342,115	9.38-15.00	11.70
Exercised	(86,100)	0.21-9.38	1.74
Terminated	(218,267)	4.69-9.38	6.44
Balance as of December 31, 2003	2,614,608	0.19-15.00	6.75
Granted	455,807	15.00-20.07	15.50
Exercised	(488,827)	0.19-9.38	3.73
Terminated	(77,096)	4.69-15.00	9.48

Balance as of December 31, 2004	2,504,492	$ 0.75-20.07	$ 8.84

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The following table summarizes information relating to the Company s stock options based upon each exercise price as of December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Options	Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
$0.75	43,334	1.6	$ 0.75	43,334	$ 0.75
$2.25	60,033	2.3	2.25	60,033	2.25
$3.75-$4.68	159,812	3.4	4.28	159,278	4.28
$4.69	562,550	4.3	4.69	502,533	4.69
$6.00-$7.50	279,835	6.2	7.24	184,866	7.14
$9.38	815,794	7.4	9.38	389,360	9.38
$15.00-$20.07	583,134	9.6	15.39	80,713	15.00
	2,504,492	6.6	$ 8.84	1,420,117	$ 6.61

In February 2004, the Company entered into an agreement with a consultant for services to be performed. In connection with such agreement, the Company granted 5,334 shares of common stock at $14.25 per share. The Company recorded deferred compensation of $76 based upon the estimated IPO filing price. The Company recorded a compensation charge of $66 in 2004. In October 2004, the Company issued 1,666 shares of common stock at $15.95 to two individuals for past services and recorded a non-cash charge of $26 in the year ended December 31, 2004.

For the years ended December 31, 2003 and 2002, the Company granted a total of 1,248 and 14,667 stock options, respectively, to certain consultants. These options were granted with 10-year terms and immediate vesting. The Company has accounted for these options in accordance with EITF 96-18, Accounting for Equity Instruments with Variable Terms That Are Issued for Consideration Other than Employee Services. Under SFAS No. 148, accordingly, the Company recorded non-cash charges of $13, $50 and $31 for the years ended December 31, 2004, 2003 and 2002, respectively. The Company determined the fair value of each option using the Black-Scholes option-pricing model utilizing the same assumptions as noted in Note 1, except for expected volatility in which the Company assumed 80% and 50%, for 2003 and 2002, respectively. Additionally, the Company granted warrants to acquire 5,000 shares of Series C preferred stock in both the years ended December 31, 2003 and 2002 in connection with the line of credit. The Company determined the fair value of each warrant using the Black-Scholes option-pricing model utilizing a risk-free interest rate of 4.30% and 4.00%, expected life of 10 years, no dividend yield and expected volatility of 80% and 0%, for 2003 and 2002, respectively. The value of the warrants was capitalized as debt issuance costs and is amortized into interest expense over the term of the line on a straight-line basis. The Company recorded non-cash charges of $80 and $21 for the years ended December 31, 2003 and 2002, respectively.

Since the Company s inception, the Company has granted to its employees options to purchase common stock at exercise prices equal to or exceeding the selling price of preferred stock. Accordingly, through September 30, 2003, no compensation expense was recorded in connection with options granted to employees. In the fourth quarter of 2003, the Company granted 35,333 options to purchase common stock at the market price of the stock the date the options were issued. The Company recorded deferred compensation of $165 based upon the midpoint of the estimated IPO filing range. In addition, in 2003 and 2002, the Company extended the option exercise period of terminated

employees as part of a severance arrangement. The Company recorded a compensation charge of $33, $501 and $159 in 2004, 2003 and 2002, respectively, which represents the difference between the fair value of the common stock and the exercise price on the date the option exercise period was extended. The fair value of the common stock was equal to the Company s fair value of preferred stock.

Employee Stock Purchase Plan. In May 2004, the Board of Directors adopted the 2004 Employee Stock Purchase Plan (2004 ESPP), under which eligible employees are permitted to purchase up to an aggregate of 500,000 shares of common stock at a discount through payroll deductions. The 2004 ESPP contains six month purchase periods. The purchase price per share will be 85% of the lower of (i) the fair market value per share of common stock on the start date of the purchase period or (ii) the fair market value per share of common stock on the purchase date. The initial offering period commenced on August 1, 2004 and ended on December 31, 2004. The Company issued 12,237 shares of common stock in 2005 under the ESPP for this initial offering period.

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The weighted average fair value for shares purchased through the employee stock purchase plan during the year ended December 31, 2004 was $3.85. The fair value of each share is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used for the year ended December 31, 2004 are as follows:

Risk-free interest rate	1.78%
Expected life (in years)	0.42
Dividend yield	
Expected volatility	39.24%

Warrants. The Company had the following warrants outstanding as of:

		December 31, 2004		December 31, 2003	
Type	**Dates of Expiration**	**Number of Warrants**	**Exercise Price Range**	**Number of Warrants**	**Exercise Price Range**
Series C				1,223,762	$ 12.50
Common	September 2005 to October 2013	148,140	$ 0.19 $9.38	317,393	$ 0.19-$9.38

In February 2004, warrants to acquire 11,764 shares of Series C preferred stock were exercised and included in the shares automatically converted into common stock as a result of the IPO in May 2004. In May 2004, warrants to acquire 32,490 shares of Series C preferred stock were exercised and included in the shares automatically converted into common stock as a result of the IPO in May 2004. In May 2004, as a result of the IPO, warrants to acquire 1,174,508 shares of Series C preferred stock were automatically exercised on a cashless basis and converted into 587,254 shares of common stock based on a conversion rate of 1.333 shares of common stock for each share of Series C. The remaining warrants to acquire 5,000 shares of Series C preferred stock were converted into warrants to acquire 6,666 shares of common stock.

Of the common stock warrants, as a result of the IPO, 72,914 warrants were automatically exercised on a cashless basis and converted into 50,124 shares of common stock. Additionally, warrants to acquire 96,339 shares of common stock were exercised into 92,174 shares of common stock during the year ended December 31, 2004. A portion of these were exercised on a cashless basis.

(10) Commitments and Contingencies

Licensing Agreement. In December 1996, the Company entered into an exclusive licensing agreement (Licensing Agreement) with a university to acquire the proprietary rights to manufacture and distribute products developed from certain university patents relating to implantable sensors. The Licensing Agreement was terminated in 2004.

Leases. In April 2004, the Company moved its administrative offices and manufacturing and distribution facilities from Frazer, Pennsylvania to West Chester, Pennsylvania. The new operating lease has a ten-year term with two five-year renewal options. As of December 31, 2004, the Company had a $550 letter of credit for a security deposit in relation to the lease.

The Company has also entered into various capital leases to acquire equipment. The capital leases have remaining terms of 1 to 52 months. The implicit lease interest rates range from approximately 4.0% to 20.0%. At December 31,

2004 and 2003, assets acquired under capital leases at a cost of $1,559 and $1,290, less accumulated amortization of $1,137 and $915, respectively, are included in property and equipment in the accompanying consolidated balance sheets.

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Future minimum payments under the operating and capital leases as of December 31, 2004, as adjusted for the amendment to the lease as noted above, are as follows:

	Operating	Capital (Note 7)
2005	$ 1,146	$ 201
2006	1,169	142
2007	1,195	92
2008	1,226	54
2009	1,257	7
Subsequent to 2009	5,680	
Total minimum lease payments	$ 11,673	496
Less amount representing interest		(82)
Present value of minimum capital lease payments		414
Less current portion		(160)
		$ 254

Rent expense was $1,156, $669 and $630 for the years ended December 31, 2004, 2003, and 2002, respectively.

Purchase Agreements. In August 2003, the Company entered into a three year agreement with one of its suppliers, as amended in 2004 and 2005. Minimum commitments under this agreement are $7,700, $9,700, $10,700, $11,200 and $11,798 for 2005, 2006, 2007, 2008 and 2009, respectively.

Employment and Change in Control Agreements. In February 2004, the Company entered into an amended employment agreement with its President and Chief Executive Officer. This employment agreement had an original expiration date of January 1, 2005 but was subject to annual one year renewals in the event that neither party notified the other party in writing of its intention not to renew the agreement no later than September 30 of the immediately preceding year. The current expiration date is January 1, 2006 but neither party has notified the other of its intention not to further extend the expiration date. The agreement provides in the event of certain terminations, as defined, all unvested stock options, restricted stock, or other awards will fully vest. Further, in the event of a change of control, vesting on 24 months of unvested shares will accelerate.

In May 2004, the Company entered into an employment agreement with its Chief Financial Officer which will expire December 31, 2006. The agreement provides for an annual salary plus incentives. In the event of termination, 12 months of unvested stock options will immediately fully vest.

The Company has also entered into agreements with each of its executive officers other than the President and Chief Executive Officer that contain provisions that will be triggered in the event of a change of control. Upon a change of control, such executive officers will receive accelerated vesting on 24-months of their then-unvested shares. In the event that such an executive officer s employment with the Company is terminated for certain reasons during the period commencing 30 days before or one-year after the date of a change of control, such executive officer will receive a lump sum payment equal to one year of his or her then-current base salary. In addition, in the event that such

an executive officer remains employed from the consummation of a change of control through the one-year anniversary of such change of control, such executive officer will receive a lump sum payment equal to one year of his or her then-current base salary. These agreements terminate if a change of control does not occur on or before December 31, 2006.

401(k) Plan. The Company maintains a 401(k) Plan for its employees. Employee contributions are voluntary. The Company may match employee contributions in amounts to be determined at the Company s sole discretion. No matching contributions have been made by the Company during the years ended December 31, 2004, 2003, and 2002.

(11) License and Development Agreements

In October 2004, the Company entered into license and development agreements with Debiotech, SA for certain technology and intellectual property. The Company acquired the exclusive worldwide license to make, use, and sell products utilizing the intellectual property portfolio owned by Debiotech, SA relating to micro-pumps and micro-needles for use related to insulin administration and in-vivo glucose sensing. The Company paid $12,000 in cash, issued 400,000 restricted shares of the Company s common stock at $14.45 per share and incurred transaction costs of $241. Additionally, upon the receipt of the requisite deliverables for 510(k) approval from the FDA for the micro-pump, providing receipt of such deliverables occurs prior to certain dates, the Company agreed to pay (i) a license fee up to $2,000 and (ii) royalties on sales of products resulting from this agreement.

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Upon the achievement of certain sale milestones for the micro-needle, the Company agreed to pay (i) a license fee up to $2,500 and (ii) royalties on sales of products resulting from this agreement.

Of the total purchase price, $14,521 was charged to expense as purchased in-process research and development and $3,500 was recorded as a non-current asset. The $14,521 was immediately charged to expense as the technology acquired will be used to develop products that have not been approved for sale by regulatory authorities, and the in-process projects to which the patents apply had not yet reached technological feasibility and had no alternative future uses. The amount capitalized, upon project success, will be evaluated and will either be charged to expense ratably over the life of the technology or will be charged to expense as in-process research and development. If the project is not successful then the full amount of the $3,500 fee will be refunded to the Company.

(12) Income Taxes

As of December 31, 2004, the Company had approximately $76,466 of net operating loss carryforwards for federal income tax purposes. These carryforwards expire between 2017 and 2024, if not utilized. In addition, the Company had state net operating loss carryforwards of approximately $45,006 in various states. Some of the state net operating losses are subject to annual limitations and expire between 2007 and 2024. At December 31, 2004, the Company has approximately $1,110 of federal research and development tax credit carryforwards, which expire between 2012 and 2024. In addition, the Company has $77 in Pennsylvania research and development tax credit carryforwards, which expire between 2017 and 2024. As of December 31, 2004, our federal net operating loss carryforwards include $1,192 related to stock-based compensation, which will be recorded as additional paid-in capital upon the recognition of the tax benefit associated with the Company s net operating loss carryforwards.

The Tax Reform Act of 1986 (the Act) provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could significantly limit the Company s ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings and the initial public offering. Accordingly, the Company s ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore the Company may not be able to take full advantage of these carryforwards for federal income tax purposes.

The components of the net deferred tax assets as of:

	December 31,	
	2004	**2003**
Deferred tax assets:		
Net operating loss carryforwards	$ 27,603	$ 23,978
License agreement	6,686	
Tax credit carryforwards	1,160	831
Warranty reserve	501	704
Property and equipment, principally due to differences in depreciation	(164)	132
Deferred revenue	212	1,686
Other	1,515	796
Total deferred tax assets	37,513	28,127
Less valuation allowance	(37,513)	(28,127)
Net deferred tax asset	$	$

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company s history of losses, the deferred tax assets are fully offset by a valuation allowance at December 31, 2004 and 2003. The valuation allowance in 2004 and 2003 increased by $9,386 and $5,139, respectively, related primarily to additional net operating losses and capitalized research and development costs incurred by the Company.

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The income tax benefit differed from the benefit computed at the U.S. statutory tax rate as follows:

	Years Ended December 31,		
	2004	2003	2002
Federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State, net of federal benefit	(4.1)	4.2	(4.3)
Provision adjustment	(16.9)		
Deemed dividend		10.4	
Other	(1.3)	(0.6)	0.5
Change in deferred tax valuation allowance	56.3	20.0	37.8
	%	%	%

(13) Related Party Transactions

One of the Company s directors is the majority owner of an insurance broker. The Company paid the insurance broker commissions of $497, $232, and $84 in 2004, 2003, and 2002, respectively, for the sale of insurance to the Company.

One of the Company s directors is a partner in the law firm that represented the Company in a lawsuit initiated against a former employee in 2003. The Company incurred fees of $19 and $23 in 2004 and 2003, respectively.

(14) Supplemental Disclosures of Cash Flow Information

For the years ended December 31, 2004, 2003, and 2002, the Company paid interest of $348, $215, and $83, respectively, and the Company also incurred $277, $122, and $190, respectively of capital lease obligations. In October 2004, the Company issued 400,000 restricted shares of its common stock at $14.45 as part of the purchase price for the Debiotech, SA transaction. These non-cash transactions are not reflected in the accompanying statement of cash flows.

(15) Business Segment

A single management team reporting to the President and Chief Executive Officer comprehensively manages the business operations of the Company. The Company does not operate separate lines of business or separate business entities with respect to any of its products. In addition, the Company does not conduct any operations outside the United States. The Company does not prepare discrete financial statements with respect to separate product areas. Accordingly, the Company does not have separately reportable segments as defined by SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. International sales were less than 10% of net revenues, and the Company has no foreign operations.

(16) Unaudited Quarterly Financial Information

	2004				2003			
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
	(in thousands except per share data)							
Net revenues	$ 4,837	$ 20,420	$ 22,654	$ 20,015	$ 7,380	$ 9,205	$ 11,291	$ 6,244
Gross margin	1,896	13,083	13,988	11,973	3,891	4,707	6,859	1,904

Net income (loss)	(8,084)	2,636	2,819	(14,033)	(4,470)	(4,704)	(2,212)	(6,418)
Deemed dividend					(4,911)	(152)		(2,815)
Net income (loss) attributable to common stockholders	$ (8,084)	$ 2,636	$ 2,819	$ (14,033)	$ (9,381)	$ (4,856)	$ (2,212)	$ (9,233)
Basic net income (loss) attributable to common stockholders per share	$ (2.01)*	$ 0.24	$ 0.15	$ (0.71)	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)
Diluted net income (loss) attributable to common stockholders per share	$ (2.01)*	$ 0.14	$ 0.14	$ (0.71)	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)

* Basic and diluted net loss per share has been revised from ($2.07).

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(17) Subsequent Event

On March 23, 2005, the Company completed its acquisition of certain assets of Cygnus, Inc. for $10,000 in cash. The assets include substantially all of Cygnus intellectual property rights, fixed assets, supplier, manufacturing and license agreements, inventory and tangible personal property. This transaction will be accounted as a purchase of assets and in-process research and development technology as the acquired assets do not constitute a business.