ANIMAS CORP
Form 424B4
May 20, 2004

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-113008
and Registration No. 333-115659

4,250,000 Shares

Common Stock

This is an initial public offering of shares of common stock by Animas Corporation. We are selling 4,250,000 shares of our common stock. The initial public offering price is $15.00 per share.

Our common stock has been approved on The NASDAQ National Market under the symbol PUMP.

This investment involves risk. See Risk Factors beginning on page 7.

	Per Share	Total
Initial Public Offering Price	$15.00	$63,750,000
Underwriting Discount	$ 1.05	$ 4,462,500
Proceeds to Animas Corporation	$13.95	$59,287,500

The underwriters have a 30-day option to purchase up to 637,500 additional shares of our common stock from us to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Piper Jaffray **JPMorgan**

Thomas Weisel Partners LLC

The date of this prospectus is May 19, 2004.

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

SUMMARY

The items in the following summary are described in more detail later in this prospectus. You should carefully read the more detailed information set out in this prospectus, the financial statements, and the related notes included elsewhere in this prospectus before investing in our common stock. In this prospectus, Animas, we, our, and us refer to Animas Corporation and its subsidiaries, unless the context requires otherwise.

Our Business

We design, develop, manufacture, and sell external insulin pumps for people with diabetes. We believe that we are the second largest supplier of pumps in the United States in terms of new pump placements. We introduced our first generation pump, the R1000, in July 2000. We began shipping our third generation pump, the IR 1200, in April 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. 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 March 31, 2004, we shipped over 14,500 pumps, 1.7 million insulin cartridges, and 1.7 million infusion sets. For the year ended December 31, 2003, our net revenues were $34.1 million, an increase of 44.6% compared to the prior year. For the three months ended March 31, 2004, our net revenues were $4.8 million, a decrease of $2.5 million, or 34%, from the comparable period in the prior year. This decrease was due to the deferral of net revenues of $4.5 million resulting from a pump upgrade program started in November 2003 and ended in March 2004. The net loss for the three months ended March 31, 2004 was $8.1 million, an increase of 80.9% from the comparable period in the prior year. We currently employ approximately 300 people, with approximately 130 of those employees directly engaged in clinical or sales activities.

Our Market

Diabetes is a chronic, life-threatening disease characterized by the body s inability to regulate blood glucose levels. More than 160 million people worldwide, approximately 3% of the population, have diabetes. For many people with diabetes, the administration of insulin, generally through injection, becomes essential to their survival. We estimate that 1% of the world s population has insulin-requiring diabetes. For these people, diabetes is difficult to manage and can be significantly debilitating.

We estimate that the size of the insulin pump and pump supplies market was over $450 million in the United States and over $650 million worldwide in 2003 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 200,000 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.

Our Solution

We differentiate ourselves through superior technology and excellent service. Our products enable people with diabetes to better manage their blood glucose levels while maintaining a more flexible lifestyle. We believe the IR 1200 is the most technologically advanced pump on the market. Our emphasis on customer service facilitates the adoption of pump therapy by patients and enhances their likelihood of success with

the therapy. Our clinical personnel supplement healthcare providers resources and participate in community diabetes education programs in order to facilitate migration to pump therapy.

IR 1200: Superior Technology

Thin profile and small size, with a footprint smaller than a business card.

Large screen and intuitive user interface.

Sturdy construction and enhanced waterproof integrity.

Long battery life.

Precise insulin delivery.

Excellent Service

High level of educational, clinical, and customer support.

Custom patient education and clinical support to complement the healthcare provider s efforts to successfully train and manage each patient.

24/7 customer support staffed with healthcare professionals providing solutions to patients and relieving the burden on healthcare providers.

We have limited market experience with our newest product, the IR 1200, as we only started shipping it in April 2004. It is possible that there could be technical or other issues of which we are not yet aware that could impact the acceptance of this product, as well as reduce the net revenues generated by this product in a particular quarter or year.

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. By leveraging superior technology and excellent service, we believe we can grow our patient 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 products. Our research and development efforts are focused on next generation pump technology, improved ancillary supplies, and ongoing development of our continuous glucose sensor;

expand the market for pump therapy and increase our market share. Our focus on education, training, and support aims to make pump therapy easier for both providers and patients;

capture sales of ancillary supplies through high patient retention. Ancillary supplies represented a significant portion of our net revenues in 2003 and during the three months ended March 31, 2004. We anticipate that ancillary supplies will remain a significant source of our net revenues in the future;

increase our international presence through expanded local distributor relationships and products with multilingual capabilities; and

enhance future profitability through gross margin improvement and organizational efficiencies.

The Offering

Common stock offered by us	4,250,000 shares
Common stock to be outstanding after this offering	18,531,753 shares
Initial public offering price per share	$15.00
Use of proceeds	We intend to use the net proceeds from this offering for additional sales and marketing efforts, research and development, expansion into international markets, repayment of outstanding bank lines of credit, and working capital and general corporate purposes. See Use of Proceeds.
NASDAQ National Market symbol	PUMP

The number of shares of our common stock to be outstanding after this offering is based on 14,281,753 shares outstanding as of April 30, 2004 and excludes:

- 159,693 shares issuable upon exercise of outstanding warrants to purchase our common stock at a weighted average exercise price of $6.61 per share; and

- 7,000,000 shares reserved for future issuance under our 2004 Equity Incentive Plan, 1998 Equity Compensation Plan, 1996 Incentive Stock Plan, and 2004 Employee Stock Purchase Plan (includes 2,580,434 shares issuable upon exercise of outstanding options at a weighted average exercise price of $7.01 per share).

All information in this prospectus assumes no exercise of the underwriters over-allotment option to purchase up to 637,500 shares of our common stock from us.

Pre-offering Transactions

Unless the context requires, all information in this prospectus reflects the following transactions, which have occurred or will occur on or before the closing of this offering (Pre-offering Transactions):

- a four-for-three split of our common stock;

- the issuance of 452,624 shares of our Series C Preferred Stock pursuant to the automatic cashless exercise of warrants, in accordance with their terms, to purchase 1,206,998 shares of our Series C Preferred Stock at an exercise price of $12.50 per share;

- the conversion, in accordance with our certificate of incorporation, of all of our shares of outstanding preferred stock (including the shares of Series C Preferred Stock issued upon the cashless exercise of the warrants discussed above) into 10,082,780 shares of our common stock;

the exercise of warrants, which otherwise expire in accordance with their terms upon the closing of this offering, to purchase 116,478 shares of our common stock at a weighted average exercise price of $4.72 per share; and

the conversion of warrants to purchase 5,000 shares of our Series C Preferred Stock into warrants to purchase 6,666 shares of our common stock.

Corporate Information

We were incorporated in Delaware in July 1996 and commenced commercial operations in July 2000. We have two wholly-owned subsidiaries, Animas Diabetes Care, LLC and Animas Holdings, Inc. Animas Diabetes Care, LLC contracts with third party payors. Animas Holdings, Inc. is a Delaware holding company, which was formed in March 2004 to better manage our investments and our intellectual property. Our principal executive offices are located at 200 Lawrence Drive, West Chester, PA 19380, and our telephone number is (610) 644-8990. Our Internet address is www.animascorp.com. The information contained on our website is not part of this prospectus.

As of April 30, 2004, we had registered the trademarks ANIMAS and EZ MANAGER with the United States Patent and Trademark Office on the Principal Register. We have applied with the United States Patent and Trademark Office to register the trademarks EZ SET, ezBolus, and CHAMPION, and the first two of these applications have been published for opposition. We use the trademarks Carb Smart™, ezWrap™, ezBG™, ezFlex Programming™, ezFlip™, PrimeSmart™, Carb Smart Plus™, and ezView™ in connection with our business. All other trademarks or service marks appearing in this prospectus are the property of their respective companies.

SUMMARY FINANCIAL DATA

The following consolidated statement of operations data for the years ended December 31, 2001, 2002, and 2003 and consolidated balance sheet data as of December 31, 2002 and 2003 have been derived from our audited consolidated financial statements and the related notes, which are included elsewhere in this prospectus. The following consolidated balance sheet data as of December 31, 2001 have been derived from our audited consolidated financial statements, which do not appear in this prospectus. The following consolidated statement of operations data for the three months ended March 31, 2003 and 2004 and consolidated balance sheet data as of March 31, 2004 have been derived from our unaudited consolidated financial statements and related notes, which are included elsewhere in this prospectus. 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 prospectus.

	Years Ended December 31,			Three Months Ended March 31,	
	2001	2002	2003	2003	2004
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Net revenues	$ 10,040	$ 23,598	$ 34,120	$ 7,380	$ 4,837(1)
Operating expenses:					
Cost of products sold	8,578	12,905	17,392	3,629	3,087
Research and development expenses	2,492	3,794	4,877	1,272	1,325
Selling, general and administrative expenses	17,638	26,347	29,463	6,913	8,405
Total operating expenses	28,708	43,046	51,732	11,814	12,817
Loss from operations	(18,668)	(19,448)	(17,612)	(4,434)	(7,980)
Interest income	294	158	22	1	1
Interest expense	(127)	(84)	(214)	(37)	(105)
Net loss	(18,501)	(19,374)	(17,804)	(4,470)	(8,084)
Deemed dividend beneficial conversion feature of preferred stock			(7,878) [2]	(4,911)	
Net loss attributable to common stockholders	$ (18,501)	$ (19,374)	$ (25,682)	$ (9,381)	$ (8,084)
Basic and diluted net loss attributable to common stockholders per share	$ (4.80)	$ (5.02)	$ (6.64)	$ (2.43)	$ (2.07)
Weighted average shares basic and diluted	3,856,649	3,861,614	3,869,844	3,867,431	3,904,769
Unaudited pro forma basic and diluted net loss attributable to common stockholders per share			$ (1.99) [3]		$ (0.58) [3]

Unaudited pro forma weighted average shares outstanding basic and diluted	12,889,179(3)	13,979,299(3)

	As of December 31,			As of March 31,
	2001	2002	2003	2004
	(in thousands)			
Balance Sheet Data:				
Cash and cash equivalents	$16,607	$ 1,134	$ 384	$ 556
Working capital	17,223	5,312	4,164	(4,736)
Total assets	23,911	15,318	23,243	26,053
Long-term debt, net of current portion	178	852	467	518
Stockholders equity	19,346	7,462	7,303	(422)

(1)See Note 2 to our consolidated financial statements regarding deferred revenue.

(2)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 7 to our consolidated financial statements.

(3)Upon closing of this offering, all outstanding shares of our preferred stock will automatically convert into shares of our common stock at a conversion rate of 1.333. The unaudited pro forma basic and diluted net loss attributable to common stockholders per share gives effect to this conversion (using the as converted method). See Note 13 to our consolidated financial statements.

RISK FACTORS

An investment in our common stock offered by this prospectus involves a substantial risk of loss. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below are the most significant risks we face. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

If the IR 1200 experiences technical issues, we could halt shipment resulting in reduced net revenues in a particular quarter or year.

We began shipping our third generation pump, the IR 1200, in April 2004. There is limited manufacturing and patient use data for the IR 1200. If the IR 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 the IR 1200, resulting in reduced net revenues in a particular quarter or year.

The failure of the IR 1200 to achieve significant market acceptance will adversely affect our business and results of operations.

The IR 1200 received Food and Drug Administration (FDA) clearance in October 2003. All of our pump sales through March 31, 2004 were attributed to predecessor pump models. We began shipping the IR 1200 in April 2004. This product is our most technologically advanced insulin pump. Until we introduce new pumps, we expect to derive substantially all of our pump net revenues from sales of the IR 1200. Our future net revenues will be negatively impacted if the IR 1200 does not achieve market acceptance. Our success depends upon the acceptance of the IR 1200 by patients, healthcare providers, and payors. Any failure to achieve significant market acceptance of the IR 1200 will adversely affect our business and results of operations.

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 our 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. Our current retention rate in terms of patients continuing to use our ancillary supplies is approximately 99%. 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 our future profitability.

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 profitability.

We have incurred losses every year since our inception in 1996. We incurred losses of $8.1 million in the three months ended March 31, 2004, $17.8 million in 2003, $19.4 million in 2002, and $18.5 million in 2001. As of March 31, 2004, we had an accumulated deficit of $91.3 million. We will need to significantly increase the net revenues we receive from sales of our products in order to achieve profitability. We may be unable to do so, and therefore may never achieve profitability. Even if we do achieve 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 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 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 1200, future generation pumps beyond the IR 1200, 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.

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. The FDA recently inspected our facility for compliance with the FDA Quality Systems Regulation (QSR). 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 inspected our facility for QSR compliance. On March 24, 2004, the FDA issued a Form FDA 483 setting forth a series of written inspectional observations of alleged QSR deviations pertaining to our R1000 and IR 1000 pumps. 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 an allegation that we have not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of our organization. The FDA investigator observed instances in which we have not adequately documented and evaluated complaints, have not conducted adequate failure investigations to determine the root cause of the complaints, and have not adequately evaluated whether appropriate corrective actions should be implemented to minimize potential risks to patients. The observations also alleged that we have not adequately established and/or followed procedures relating to various activities such as document control, product and equipment testing, software validation and employee training.

On April 14, 2004, we submitted a written response to the FDA indicating the corrective actions that we have taken and that we will take in response to the FDA s observations. 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, which would adversely affect our net revenues and our future profitability.

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 pre-market approval (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 and IR 1000 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.

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.

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 MiniMed 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 during 2004.

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.

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 and results of operations 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 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 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.

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:

- 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 and reducing our operating results.

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:

certification of our new facility in order to retain the CE conformity marking for our products that are shipped to patients in countries that are members of the European Union;

fluctuations in foreign currencies;

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.

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.

Risks Associated with this Offering

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of your stock.

Upon the closing of this offering, our amended and restated certificate of incorporation and bylaws will contain provisions that could delay or prevent our change in control. Some of these provisions:

authorize the issuance of preferred stock which can be created and issued by our board of directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of our common stock;

prohibit stockholder actions by written consent; and

provide for a classified board of directors.

In addition, the provisions of Section 203 of the Delaware General Corporate Law govern us. These provisions may prohibit stockholders owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our amended and restated certificate of incorporation and bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in our market price being lower than it would be without these provisions.

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

Following this offering, the price at which our common stock will trade may be volatile. The market price of our common stock could be 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.

Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and make it difficult for you to recover the full value of your investment in our shares.

If our existing stockholders sell substantial amounts of our common stock in the public market following this offering or if there is a perception that these sales may occur, the market price of our common stock could decline. Upon closing of this offering, we will have outstanding 18,531,753 shares of our common stock. Of these shares, only the shares of our common stock (plus any of the shares purchased pursuant to the exercise of the underwriters over-allotment option) sold in this offering will be freely tradeable, without restriction, in the public market. We have obtained lockup agreements from our current stockholders representing approximately 94% of our outstanding common stock preventing those stockholders from selling their stock for a period of 180 days from the date of this prospectus.

After the lockup agreements pertaining to this offering expire 180 days from the date of this prospectus, unless waived, approximately 13.4 million additional shares will be eligible for sale in the public market at various times, subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended

(Securities Act). Holders of substantially all of such shares of our common stock have the right to require us to register such shares for sale under the Securities Act in certain circumstances and also have the right to include those shares in a registration initiated by us. If we are required to include the shares of our common stock of these stockholders pursuant to these registration rights in a registration initiated by us, sales made by such stockholders may adversely affect the price of our common stock and our ability to raise needed capital. In addition, if these stockholders exercise their demand registration rights and cause a large number of shares to be registered and sold in the public market or demand that we register their shares on a shelf registration statement, such sales or shelf registration may have an adverse effect on the market price of our common stock.

Following this offering, we also intend to file one or more registration statements with the Securities and Exchange Commission (SEC) covering a total of 7,000,000 shares of our common stock available for future issuance under our 2004 Equity Incentive Plan, 1998 Equity Compensation Plan, 1996 Incentive Stock Plan, and 2004 Employee Stock Purchase Plan. Upon effectiveness of such registration statements, any shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lockup agreements referred to above and subject to compliance with Rule 144 in the case of our affiliates. Sales of a large number of shares of our common stock issued under these plans in the public market may have an adverse effect on the market price of our common stock. For more information regarding the sale of shares subsequently issued under such plans and the permissible sale of our common stock by existing stockholders after the closing of this offering, see Shares Eligible for Future Sale.

Concentration of ownership among our existing directors, executive officers, and principal stockholders may prevent new investors from influencing significant corporate decisions.

Upon closing of this offering, our current directors, executive officers, principal stockholders, and their affiliates will, in the aggregate, beneficially own approximately 46% of our outstanding common stock. As a result, these stockholders will be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. These stockholders may support proposals and actions with which you may disagree or which are not in your interests.

You will incur immediate and substantial dilution as a result of this offering.

The initial public offering price is substantially higher than the book value per share of our common stock. As a result, purchasers in this offering will experience immediate and substantial dilution of $11.92 per share in the tangible book value of our common stock from the initial public offering price. In addition, to the extent that currently outstanding options to purchase common stock are exercised, there will be further dilution. See Dilution.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Business, may contain forward-looking statements. These statements may relate to, but are not limited to, expectations of future operating results or financial performance, capital expenditures, introduction of new products, regulatory compliance, plans for growth, and future operations, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These risks and other factors include, but are not limited to, those listed under Risk Factors. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expect, plan, anticipate, believe, estimate, predict, intend, potential, continue, or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties and actual results may differ materially from those discussed as a result of various factors, including those factors described in the Risk Factors section of this prospectus. Except as required by applicable law, including the securities laws of the United States, and the rules and regulations of the SEC, we do not plan to publicly update or revise any forward-looking statements after we distribute this prospectus, whether as a result of any new information, future events, or otherwise.

Potential investors should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the Risk Factors section and elsewhere in this prospectus could harm our business, prospects, operating results, and financial condition.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 4,250,000 shares of our common stock that we are selling in this offering will be approximately $57.0 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters over-allotment option is exercised in full, we estimate that we will receive net proceeds of approximately $65.9 million.

We currently estimate that we will use the net proceeds of this offering, together with our cash on hand and cash generated from operations, to fund our operations, including:

- approximately $1.0 million for continued sales and marketing efforts for the IR 1200;
- approximately $5.0 million for research and development of further enhancements to the IR 1200, future generation pumps, infusion sets, and our continuous glucose sensor;
- approximately $1.0 million for expansion into international markets;
- approximately $4.0 million for repayment of outstanding bank lines of credit; and
- approximately $46.0 million for working capital and general corporate purposes.

As of March 31, 2004, our outstanding bank lines of credit bore interest at 5.5% and 5.75% and had maturity dates of January 5, 2005 and May 5, 2005, respectively. These bank lines of credit were used for short-term funding for working capital purposes.

The amounts actually expended for these purposes may vary significantly and will depend on a number of factors, including the amount of our future net revenues, expenses, and the other factors described under Risk Factors. Should we determine to employ cash resources for the acquisition of complementary businesses, products, or technologies, the amounts available for the purposes cited above may be significantly reduced. Although we evaluate potential acquisitions in the ordinary course of business, we have no specific understandings, commitments, or arrangements with respect to any acquisition or investment at this time.

Until we use the net proceeds of this offering for the above purposes, we intend to contribute the funds to a wholly owned subsidiary, which will invest the funds in short-term, investment grade, and interest-bearing securities. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table describes our capitalization as of March 31, 2004. Our capitalization is presented:

- on an actual basis;
- on a pro forma basis to give effect to the Pre-offering Transactions; and
- on a pro forma as adjusted basis to give effect to the Pre-offering Transactions and the sale by us of 4,250,000 shares of our common stock in this offering and the application of the net proceeds from the sale (after deducting offering expenses and underwriting discounts and commissions).

You should read the capitalization table together with the sections of this prospectus entitled Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and with our consolidated financial statements and related notes included elsewhere in this prospectus.

	At March 31, 2004		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except for share and per share data)		
Long-term debt, net of current portion	$ 518	$ 518	$ 518
Preferred stock, $0.01 par value; authorized zero shares (actual and pro forma) 10,000,000 shares (pro forma as adjusted); none issued			
Series A, B, and C Preferred stock, $0.01 par value; authorized 8,353,200 shares (actual and pro forma) zero shares (pro forma as adjusted); issued and outstanding 7,109,488 shares (actual); none (pro forma and pro forma as adjusted).	71		
Common stock, $0.01 par value; authorized 100,000,000 shares (actual, pro forma and pro forma as adjusted); issued and outstanding 4,082,495 shares (actual); 14,281,753 shares (pro forma); 18,531,753 shares (pro forma as adjusted)	41	143	185
Additional paid-in capital	90,951	91,470	148,466
Deferred compensation	(227)	(227)	(227)
Accumulated deficit	(91,258)	(91,258)	(91,258)
Total stockholders equity (deficit)	(422)	128	57,166
Total capitalization	$ 96	$ 646	$ 57,684

The outstanding share information in the table above is based on the number of shares of our common stock outstanding as of March 31, 2004. This table excludes:

- 159,693 shares issuable upon exercise of outstanding warrants to purchase our common stock at a weighted average exercise price of $6.61 per share; and
- 7,000,000 shares reserved for future issuance under our 2004 Equity Incentive Plan, 1998 Equity Compensation Plan, 1996 Incentive Stock Plan, and 2004 Employee Stock Purchase Plan (includes 2,558,318 shares issuable upon exercise of outstanding options at a weighted average exercise price of $6.93 per share as of March 31, 2004).

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

The pro forma net tangible book value of our common stock as of March 31, 2004 was approximately $128,000 or $0.01 per share after giving effect to the following transactions, which have occurred or will occur on or before the closing of this offering (Pre-offering Transactions):

- a four-for-three split of our common stock (included in actual);
- the issuance of 452,624 shares of our Series C Preferred Stock pursuant to the automatic cashless exercise of warrants, in accordance with their terms, to purchase 1,206,998 shares of our Series C Preferred Stock at an exercise price of $12.50 per share;
- the conversion, in accordance with our certificate of incorporation, of all of our shares of outstanding preferred stock (including the shares of Series C Preferred Stock issued upon the cashless exercise of the warrants discussed above) into 10,082,780 shares of our common stock;
- the exercise of warrants, which otherwise expire in accordance with their terms upon the closing of this offering, to purchase 116,478 shares of our common stock at a weighed average exercise price of $4.72 per share; and
- the conversion of warrants to purchase 5,000 shares of our Series C Preferred Stock into warrants to purchase 6,666 shares of our common stock.

Pro forma net tangible book value per share represents our total assets less total liabilities, divided by the number of pro forma shares of common stock outstanding.

Without taking into account any changes in pro forma net tangible book value after March 31, 2004, other than to give effect to the sale by us of the 4,250,000 shares of our common stock in this offering and the application of the estimated net proceeds therefrom (after deducting estimated offering expenses and the underwriting discounts and commissions), our as adjusted pro forma net tangible book value as of March 31, 2004 would have been $57.2 million, or $3.08 per share.

This represents an immediate increase in pro forma net tangible book value of $3.07 per share to existing stockholders and an immediate dilution of $11.92 per share to purchasers of our common stock in this offering. The following table illustrates this per share dilution:

Initial public offering price per share	$15.00
Actual net tangible book value (deficit) per share at March 31, 2004	(0.10)
Increase attributable to Pre-offering Transactions	0.11
Pro forma net tangible book value per share at March 31, 2004	0.01
Increase in pro forma net tangible book value per share attributable to this offering	3.07
Adjusted pro forma net tangible book value per share after this offering	3.08
Dilution per share to new investors	$11.92

If the underwriters exercise their over-allotment option in full, adjusted pro forma net tangible book value per share after this offering would be $3.45, the increase in pro forma net tangible book value per share to existing stockholders would be $3.44 per share and the dilution to new investors would be $11.55 per share.

The following table sets forth, on a pro forma basis as of March 31, 2004, giving effect to the Pre-offering Transactions, the number of shares of our common stock purchased from us, the total consideration paid to us, the average price per share paid by existing stockholders, and the new investors.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	14,281,753	77.1%	$ 82,138,000	56.3%	$ 5.75
New investors	4,250,000	22.9	63,750,000	43.7	15.00
Total	18,531,753	100.0%	$145,888,000	100.0%	

The table above assumes no exercise of stock options to purchase common stock as of March 31, 2004. At March 31, 2004, there were 2,558,318 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted-average exercise price of $6.93 per share. In addition, the table above assumes no exercise of certain warrants as of March 31, 2004. Such warrants excluded from the above table include 159,693 shares of common stock issuable upon the exercise of those outstanding warrants at a weighted-average exercise price of $6.61.

If all of the options and warrants are exercised, there would be further dilution to new investors as follows:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	14,281,753	67.2%	$ 82,138,000	49.9%	$ 5.75
Shares subject to options and warrants	2,718,008	12.8	18,828,000	11.4	6.93
New investors	4,250,000	20.0	63,750,000	38.7	15.00
Total	21,249,761	100.0%	$164,716,000	100.0%	

SELECTED FINANCIAL DATA

The following consolidated statement of operations data for the years ended December 31, 2001, 2002, and 2003 and consolidated balance sheet data as of December 31, 2002 and 2003 have been derived from our audited consolidated financial statement and the related notes, which are included elsewhere in this prospectus. The statement of operations data for the years ended December 31, 1999 and 2000, and the balance sheet data as of December 31, 1999, 2000, and 2001 were derived from our audited financial statements, which do not appear in this prospectus. The following consolidated statement of operations for the three months ended March 31, 2003 and 2004 and the consolidated balance sheet data as of March 31, 2004 have been derived from our unaudited consolidated financial statements and related notes, which are included elsewhere in this prospectus. When you read this selected financial data, it is important that you also read the historical consolidated financial statements and related notes included in this prospectus, as well as the section of this prospectus related to Management s Discussion and Analysis of Financial Condition and Results of Operations. Historical results are not necessarily indicative of future results.

	Years Ended December 31,					Three Months Ended March 31,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands, except share and per share data)						
Statement of Operations Data:							
Net revenues	$ 105	$ 1,821	$ 10,040	$ 23,598	$ 34,120	$ 7,380	$ 4,837(1)
Cost of products sold	22	1,983	8,578	12,905	17,392	3,629	3,087
Research and development expenses	3,092	2,737	2,492	3,794	4,877	1,272	1,325
Selling, general and administrative expenses	2,058	7,804	17,638	26,347	29,463	6,913	8,405
Total operating expenses	5,172	12,524	28,708	43,046	51,732	11,814	12,817
Loss from operations	(5,067)	(10,703)	(18,668)	(19,448)	(17,612)	(4,434)	(7,980)
Interest income	5	204	294	158	22	1	1
Interest expense	(60)	(153)	(127)	(84)	(214)	(37)	(105)
Net loss	$ (5,122)	$ (10,652)	$ (18,501)	$ (19,374)	$ (17,804)	$ (4,470)	$ (8,084)
Deemed dividend beneficial conversion feature of preferred stock					(7,878) (2)	(4,911)	
Net loss attributable to common stockholders	$ (5,122)	$ (10,652)	$ (18,501)	$ (19,374)	$ (25,682)	(9,381)	$ (8,084)
Basic and diluted net loss attributable to common stockholders	$ (1.55)	$ (2.88)	$ (4.80)	$ (5.02)	$ (6.64)	$ (2.43)	$ (2.07)

Weighted average shares basic and diluted	3,315,091	3,700,197	3,856,649	3,861,614	3,869,844	3,867,431	3,904,769
Unaudited pro forma basic and diluted net loss attributable to common stockholders per share					$ (1.99) (3)		$ (0.58) (3)
Unaudited pro forma weighted average shares outstanding basic and diluted					12,889,179(3)		13,979,299(3)

	As of December 31,					As of March 31,
	1999	2000	2001	2002	2003	2004
	(in thousands)					
Balance Sheet Data:						
Cash and cash equivalents	$1,320	$ 432	$16,607	$ 1,134	$ 384	$ 556
Working capital	454	(639)	17,223	5,312	4,164	(4,736)
Total assets	2,178	4,667	23,911	15,318	23,243	26,053
Long-term debt, net of current portion	157	281	178	852	467	518
Stockholders equity (deficit)	(726)	397	19,346	7,462	7,303	(422)

(1) See Note 2 to our consolidated financial statements regarding deferred revenue.

(2) 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 7 to our consolidated financial statements.

(3) Upon closing of this offering, all outstanding shares of our preferred stock will automatically convert into shares of our common stock at a conversion rate of 1.333. The unaudited pro forma basic and diluted net loss attributable to common stockholders per share gives effect to this conversion (using the as converted method). See Note 13 to our consolidated financial statements.

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 prospectus. 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 prospectus.

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. We also provide ancillary supplies necessary for pump therapy, including insulin cartridges, infusion sets, batteries, and various accessories.

Since we began commercial operations in July 2000 through March 31, 2004, we shipped over 14,500 pumps, 1.7 million insulin cartridges, and 1.7 million infusion sets. Our total net revenues were $34.1 million and $4.8 million for the year ended December 31, 2003 and the three months ended March 31, 2004, respectively.

Our approximate 65-person direct sales force promotes our pump in the United States to healthcare professionals and patients. In addition, our approximate 65 diabetes educators, or clinical managers, train and provide clinical support to patients in the United States. We use distributors to market, sell, and service our products outside the United States.

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 2003, approximately 80% to 85% of our annual net revenues were generated by direct sales 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 selling price for such product and the contractual allowance given to the healthcare payor.

Pump Upgrade Program. In November 2003, we implemented a program that allows patients in the United States to upgrade their IR 1000 pump purchased between November 1, 2003 and March 31, 2004, at their option and at no additional cost, to the IR 1200 insulin pump when it becomes available. 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. As a result, we were not in compliance with certain covenants under our credit facility with a bank, including a minimum net worth requirement. We sought from the bank and were subsequently granted a waiver with respect to all such defaults. We are now in compliance with all covenants under the credit facility and we expect to remain in compliance throughout 2004. We do not anticipate the need for additional product upgrade programs in the foreseeable future. We began shipping the IR 1200 pump in April 2004, and based on current estimates, we expect that our obligations to ship upgraded pumps under the upgrade program will be satisfied by July 31, 2004.

In accordance with generally accepted accounting principles, we have deferred the recognition of all net revenues for IR 1000 pumps shipped under the upgrade program. We will not recognize the net revenue on an IR 1000 pump shipped under this program until either the IR 1200 replacement pump is shipped to the patient requesting an upgrade or the patient has declined the upgrade. All IR 1000 pumps shipped to new patients domestically between November 1, 2003 and March 31, 2004 are subject to this upgrade program. We have also deferred the associated cost of products sold on shipments of pumps under the

upgrade program. Net revenues will be recognized when we ship the IR 1200 pump to the patient or when the patient declines to be part of the upgrade program. The deferred cost represents the recoverable inventory costs of the IR 1000 pumps when they are returned to us. When we ship an IR 1200 as a replacement pump, we will record the cost of the IR 1200 pump as cost of products sold at that time.

We project that our obligations under this program to upgrade IR 1000 pumps to IR 1200 pumps will be satisfied by July 31, 2004. As a result of this program, our net revenues for the second and third quarters of 2004 will be increased by the recognition of net revenues deferred from previous quarters, as we ship upgraded pumps or patients decline the upgrade. A delay or acceleration of our obligations under this upgrade program in a given period will cause a corresponding postponement or an acceleration, respectively, of net revenues in a given period.

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 expensed 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.

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 accounting principles generally accepted in the United States. 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 Note 2 to 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.

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 pump 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.

In 2003, approximately 80% to 85% of our products were sold directly to patients. We bill these patients directly or 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 selling price 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.

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.

Three Months Ended March 31, 2003 and 2004

Results of Operations. The following tables set forth, for the quarters 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.

	Three Months Ended March 31,					
	2003		2004		Change, 2004/2003	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$ 7,380	100.0%	$ 4,837	100.0%	$(2,543)	(34.5)%
Operating expenses:						
Cost of products sold	3,629	49.2	3,087	63.8	(542)	(14.9)
Research and development expenses	1,272	17.2	1,325	27.4	53	4.2
Selling, general and administrative expenses	6,913	93.7	8,405	173.8	1,492	21.6
Total operating expenses	11,814	160.1	12,817	265.0	1,003	8.5
Loss from operations	(4,434)	(60.1)	(7,980)	(165.0)	(3,546)	80.0
Interest income	1		1			
Interest expense	(37)	(0.5)	(105)	(2.2)	(68)	183.8
Net loss	(4,470)	(60.6)	(8,084)	(167.1)	(3,614)	80.9
Deemed dividend	(4,911)	(66.5)			4,911	(100.0)
Net loss attributable to common stockholders	$ (9,381)	(127.1)%	$ (8,084)	(167.1)%	$ 1,297	13.8%
Net Revenues, Cost of Products Sold and Gross Margin						
Net Revenues						
Insulin pumps	$ 4,962	67.2%	$ 1,171	24.2%	$(3,791)	(76.4)%
Ancillary supplies	2,418	32.8	3,666	75.8	1,248	51.6
Total	$ 7,380	100.0%	$ 4,837	100.0%	$(2,543)	(34.5)%
Cost of Products Sold						
Insulin pumps	$ 1,858	51.2%	$ 984	31.9%	$ (874)	(47.0)%
Ancillary supplies	1,771	48.8	2,103	68.1	332	18.7
Total	$ 3,629	100.0%	$ 3,087	100.0%	$ (542)	(14.9)%
Gross Margin						
Insulin pumps	$ 3,104	82.8%	$ 187	10.7%	$(2,917)	(94.0)%
Ancillary supplies	647	17.2	1,563	89.3	916	141.6
Total	$ 3,751	100.0%	$ 1,750	100.0%	$(2,001)	(53.3)%
Gross Margin %						
Insulin pumps		62.6%		16.0%		

Ancillary supplies	26.8%	42.6%
Total	50.8%	36.2%

Net Revenues. In the first three months of 2004, net revenues decreased by $2.5 million, or 34.5%, to $4.8 million from $7.4 million from the comparable period in 2003. The decrease in net revenues was a result of our decision to establish a pump upgrade program in November 2003. This upgrade program caused us to defer net revenues on shipments until the upgraded pumps are shipped as part of the program. For the three months ended March 31, 2004, we deferred $4.5 million of net revenues due to the program. Additionally, we decided to stop shipments of orders accepted in the last three weeks of the quarter in anticipation of the launch of the IR 1200 in April 2004. As of March 31, 2004, we had $2.3 million of unfulfilled orders which were shipped in April 2004. Net revenues from domestic and foreign sales were $4.1 million and $0.7 million, respectively, in the three months ended March 31, 2004

and $6.7 million and $0.7 million, respectively, in the comparable period in 2003. Pump net revenues decreased by $3.8 million due to the upgrade program and the decision not to ship product in late March 2004. Our average selling price of pumps remained relatively stable over this period.

Ancillary supplies net revenues, consisting of infusion sets, pump cartridges, and other ancillary supplies increased by 51.6% in the three months ended March 31, 2004 versus the comparable period of 2003. The increase in net revenues for ancillary supplies was due to increased unit sales, while prices remained near prior period levels. The growth in net revenues in ancillary supplies reflected our growth in the installed base of patients using our pumps in the comparable three month period of 2004 and 2003 and our retention of patients from prior years.

We expect that our obligations under the pump upgrade program will be satisfied by July 31, 2004. As a result, our net revenues in the second and third quarter of 2004 will benefit from the end of the upgrade program and the recognition of net revenues upon shipment of the product or when the patient declines to be part of the upgrade program. Additionally, all unfulfilled pump orders from March 2004 were shipped in April 2004.

Cost of Products Sold. Cost of products sold decreased $542,000, or 14.9%, to $3.1 million in the three months ended March 31, 2004 from $3.6 million in the comparable period of 2003. This decrease reflected the decrease in net revenues in the three months ended March 31, 2004 from the comparable period of 2003. However, as a percentage of net revenues, cost of products sold increased to 63.8% in 2004 from 49.2% in 2003. The primary factor that contributed to the increased percentage was the pump upgrade program. Although we deferred recoverable costs associated with the deferral of pump revenues, non-recoverable costs such as shipping were charged to costs of products sold. Partially offsetting the increase in cost percentage were improved purchasing efficiencies for ancillary supplies, a trend that carried over from earlier periods.

Gross Margin. Gross margin decreased to 36.2% in the three months ended March 31, 2004 from 50.8% in the comparable period of 2003. Gross margin for pumps decreased to 16.0% in 2004 due to lower absorption of overhead due to the pump upgrade program. Ancillary supplies gross margin increased to 42.6% in the three months ended March 31, 2004 from 26.8% in the comparable period of 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 improve in 2004. It is expected that this improvement will result from the expected increase in net revenues and the expected decrease in costs of raw materials and better absorption of overhead. Additionally, it is anticipated that the combination of the expected increase in ancillary supplies net revenues, as the patient base expands, and the expected decrease in the costs of ancillary supplies will favorably impact the anticipated gross margin and gross margin percentage for the remainder of 2004.

Research and Development. Research and development expenses increased $53,000, or 4.2%, to $1.3 million for the three months ended March 31, 2004 from $1.3 million in the comparable period of 2003 reflecting increased spending on activities to improve existing products and develop new products. As a percentage of net revenues, research and development expenses increased to 27.4% for the three months ended March 31, 2004 from 17.2% in the comparable period of 2003. The percentage increase in net revenues resulted primarily from the pump upgrade program. In future quarters, we expect research and development expenditures as a percentage of net revenues to decline due the end of the pump upgrade program, and the growth of our net revenues.

Selling General and Administrative Expenses. Selling, general and administrative (SG&A) expenses increased by $1.5 million, or 21.6%, to $8.4 million in the three months ended March 31, 2004 from $6.9 million in the comparable period of 2003. Of this increase, $670,000 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. In addition, higher administrative personnel costs of $304,000 and professional fees of $24,000 contributed to higher SG&A costs in the three months ended March 31, 2004.

We expect SG&A expenses to continue to increase for the remainder of 2004 as compared to 2003 in absolute dollars as we expand our sales, clinical, and marketing efforts to support our growing business. Also, we expect to incur additional costs as we operate as a public company. However, we expect that SG&A expenses should continue to decline as a percentage of net revenues as we continue to leverage our SG&A infrastructure.

Interest Expense. Interest expense increased to $105,000 in the three months ended March 31, 2004 from $37,000 in the comparable period of 2003. This reflects a higher outstanding debt balance in the comparable periods. The increase in average debt was primarily the result of higher borrowing under our credit lines.

Deemed Dividend Beneficial Conversion Feature of Preferred Stock. In connection with issuances of preferred stock in the three months ended March 31, 2003, we recorded a non-cash charge of $4.9 million that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock (see Note 7 to our consolidated financial statements). There was no similar item in the three months ended March 31, 2004.

Years Ended December 31, 2002 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.

	Year Ended December 31,					
	2002		2003		Change, 2003/2002	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$ 23,598	100.0%	$ 34,120	100.0%	$ 10,522	44.6%
Operating expenses:						
Cost of products sold	12,905	54.7	17,392	51.0	4,487	34.8
Research and development expenses	3,794	16.1	4,877	14.3	1,083	28.5
Selling, general and administrative expenses	26,347	111.6	29,463	86.4	3,116	11.8
Total operating expenses	43,046	182.4	51,732	151.6	8,686	20.2
Loss from operations	(19,448)	(82.4)	(17,612)	(51.6)	1,836	(9.4)
Interest income	158	0.7	22	0.1	(136)	(86.1)
Interest expense	(84)	(0.4)	(214)	(0.6)	(130)	154.8
Net loss	(19,374)	(82.1)	(17,804)	(52.2)	1,570	(8.1)
Deemed dividend			(7,878)	(23.1)	(7,818)	(100)
Net loss attributable to common stockholders	$ (19,374)	(82.1)%	$ (25,682)	(75.3)%	$ 9,448	32.6%
Net Revenues, Cost of Products Sold and Gross Margin						
Net Revenues						
Insulin pumps	$ 17,763	75.3%	$ 21,176	62.1%	$ 3,413	19.2%
Ancillary supplies	5,835	24.7	12,944	37.9	7,109	121.8
Total	$ 23,598	100.0%	$ 34,120	100.0%	$ 10,522	44.6%
Cost of Products Sold						
Insulin pumps	$ 8,334	64.6%	$ 8,647	49.7%	$ 313	3.8%
Ancillary supplies	4,571	35.4	8,745	50.3	4,174	91.3
Total	$ 12,905	100.0%	$ 17,392	100.0%	$ 4,487	34.8%
Gross Margin						
Insulin pumps	$ 9,429	88.2%	$ 12,529	74.9%	$ 3,100	32.9%
Ancillary supplies	1,264	11.8	4,199	25.1	2,935	232.2
Total	$ 10,693	100.0%	$ 16,728	100.0%	$ 6,035	56.4%
Gross Margin %						

Insulin pumps	53.1%	59.2%
Ancillary supplies	21.7%	32.4%
Total	45.3%	49.0%

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 permits 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 becomes 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 $5.2 million and the related cost associated with deferred revenue of $1.0 million.

We anticipate similar growth in net revenues for pumps and ancillary supplies shipped in 2004 from 2003 as compared to the growth in 2003 from 2002. Additionally, we expect that this growth will be increased by the recognition in 2004 of net revenues deferred in 2003. In addition, the timing of the recognition of these deferred net revenues should have a significant effect on the quarterly pattern of our operating results in 2004 compared to 2003. We do not expect that there will be a similar upgrade program during 2004 that would result in a deferral of revenues from 2004 into 2005.

Cost of Products Sold. Cost of products sold increased $4.5 million, or 34.8%, to $17.4 million in 2003 from $12.9 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 51.0% in 2003 from 54.7% 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 $313,000, or 3.8%, 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. While we expect that cost of products sold in 2004 will increase along with the expected increase in net revenues, we expect that cost of products sold as a percent of net revenues will continue to decrease in 2004 from 2003 as we continue to benefit from economies of scale.

Gross Margin. Gross margin improved to 49.0% in 2003 from 45.3% in 2002. Gross margin for pumps improved to 59.2% in 2003 from 53.1% 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. Supplies gross margin increased to 32.4% in 2003 from 21.7% in 2002. Gross margin improvement for ancillary supplies was due to lower cost sources of supplies.

It is anticipated that the gross margin and gross margin percentage will continue to improve in 2004. Reasons for this improvement relate to the expected increase in net revenues and the decreased costs of raw materials, absorption of overhead, and improved yields associated with pump net revenues and manufacturing. Additionally, it is anticipated that the combination of the expected increase in ancillary supplies net revenues, as the customer base expands, and the expected decrease in the costs of ancillary supplies will favorably impact the anticipated gross margin and gross margin percentage for 2004.

Research and Development. Research and development expenses increased $1.1 million, or 28.5%, to $4.9 million in 2003 from $3.8 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 14.3% in 2003 from 16.1% in 2002 due to the significant increase in net revenues in 2003 from the prior year. Although we anticipate a similar increase in research and development costs in 2004 from 2003 as compared to the increase in 2003 from 2002, we also anticipate a decrease in these

costs as the percentage of net revenues. In 2004, 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 2004 is allocated towards development of long-term products, including our continuous glucose sensor.

Selling, General and Administrative Expenses. SG&A expenses increased $3.1 million, or 11.8%, to $29.5 million in 2003 from $26.3 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 86.4% of net revenues from 111.6% from 2002. This decline was largely due to our continuing ability to gain economies of scale related to our significant growth in net revenues. We expect SG&A expenses to increase in absolute dollars in 2004 from 2003 as we expand our sales, clinical, and marketing efforts to support our growing business. Also, we expect to incur additional operational costs as we operate as a public company. 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.

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, which begin to expire in 2012, that are available to reduce future taxable income. We also have $34.4 million of state carryforwards that are subject to a $2.0 million annual limitation 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 2002 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 (see Note 7 to our consolidated financial statements).

Years Ended December 31, 2001 and 2002

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.

	Year Ended December 31,					
	2001		2002		Change, 2002/2001	
	$	%	$	%	$	%
	(in thousands)					
Consolidated Statements of Operations						
Net revenues	$ 10,040	100.0%	$ 23,598	100.0%	$ 13,558	135.0%
Operating expenses:						
Cost of products sold	8,578	85.4	12,905	54.7	4,327	50.4
Research and development expenses	2,492	24.8	3,794	16.1	1,302	52.2
Selling, general and administrative expenses	17,638	175.7	26,347	111.6	8,709	49.4
Total operating expenses	28,708	285.9	43,046	182.4	14,338	49.9
Loss from operations	(18,668)	(185.9)	(19,448)	(82.4)	(780)	4.2
Interest income	294	2.9	158	0.7	(136)	(46.3)
Interest expense	(127)	(1.3)	(84)	(0.4)	43	(33.9)
Net loss	$ (18,501)	(184.3)%	$ (19,374)	(82.1)%	$ (873)	4.7%
Net Revenues, Cost of Products Sold and Gross Margin						
Net Revenues						
Insulin pumps	$ 8,296	82.6%	$ 17,763	75.3%	$ 9,467	114.1%
Ancillary supplies	1,744	17.4	5,835	24.7	4,091	234.6
Total	$ 10,040	100.0%	$ 23,598	100.0%	$ 13,558	135.0%
Cost of Products Sold						
Insulin pumps	$ 6,949	81.0%	$ 8,334	64.6%	$ 1,385	19.9%
Ancillary supplies	1,629	19.0	4,571	35.4	2,942	180.6
Total	$ 8,578	100.0%	$ 12,905	100.0%	$ 4,327	50.4%
Gross Margin						
Insulin pumps	$ 1,347	92.1%	$ 9,429	88.2%	$ 8,082	600.0%
Ancillary supplies	115	7.9	1,264	11.8	1,149	999.1
Total	$ 1,462	100.0%	$ 10,693	100.0%	$ 9,231	631.4%
Gross Margin %						
Insulin pumps		16.2%		53.1%		
Ancillary supplies		6.6%		21.7%		
Total		14.6%		45.3%		

Net Revenues. Net revenues increased $13.6 million, or 135.0%, in 2002 to $23.6 million from $10.0 million in 2001, which reflected continued growth in the overall market for insulin pumps, an increase in our share of the market, and our larger installed base of our customers in 2002 compared to 2001. Net revenues for domestic and foreign sales were $23.0 million and $592,000, respectively, in 2002 and $9.8 million and $216,000, respectively, in 2001. Pump net revenues increased by $9.5 million, or 114.1%, in 2002 from 2001. The increase in pump net revenues was due to an increase in unit shipments. Most of the increase in pump net revenues in this period can be attributed to an increase in unit sales of pumps. Our average selling price of pumps remained relatively stable over this period. Sales of ancillary supplies increased 234.6% in 2002 from 2001 reflecting the continued growth in the installed base of our pumps that are being used by patients.

Cost of Products Sold. Cost of products sold increased $4.3 million, or 50.4%, to $12.9 million in 2002 from $8.6 million in 2001, which reflected higher costs associated with the increase in sales volume. As a percent of net revenues, however, cost of products sold declined to 54.7% in 2002 from 85.4% in 2001. This decrease reflected improvements in our manufacturing yields, better efficiency of manufacturing labor, and absorption of manufacturing overhead costs. The cost of supplies increased by $2.9 million, or 180.6%, compared to 2001. The increase in cost of supplies from 2002 to 2001 was lower than the increase in the net revenues for these products due to a reduction in the cost of the products.

Gross Margin. Gross margin improved to 45.3% in 2002 from 14.6% in 2001. Margin for pumps improved to 53.1% in 2002 from 16.2% in 2001. Margin improvement for pumps reflected better yields in the manufacture of pumps, improved efficiencies in labor, and better absorption of overhead due to increased volumes. Ancillary supplies gross margin increased to 21.7% in 2002 from 6.6%. The improvement in margin of supplies was due to decreased unit cost of supplies.

Research and Development. Research and development expenses increased $1.3 million, or 52.2%, to $3.8 million in 2002 from $2.5 million in 2001. Increases in salary and related personnel expenses associated with increases in headcount and higher prototype development costs were the major reasons for the increase. As a percent of net revenues, research and development expenditures declined to 16.1% in 2002 from 24.8% in 2001.

Selling, General and Administrative Expenses. SG&A expenses increased $8.7 million, or 49.4%, to $26.3 million in 2002 from $17.6 million in 2001. The increase was primarily related to higher salary and fringe benefit costs associated with increased headcount in the sales, clinical, and marketing functions as well as a significant increase in sales commissions. The increase in the sales and marketing functions as well as the increase in commissions were consistent with the increase in volume of sales. In addition, expenses associated with demo units, brochures, videos, and other promotional items increased significantly in 2002 from 2001, reflecting ongoing efforts to raise awareness of the benefits of our products. As a percent of net revenues, SG&A expenses declined to 111.6% in 2002 from 175.7% in 2001, reflecting the economies of scale realized in these areas.

Interest Income. Interest income decreased to $158,000 in 2002 from $294,000 in 2001 reflecting lower average cash and cash equivalents balances in 2002 compared to 2001.

Interest Expense. Interest expense declined to $84,000 in 2002 from $127,000 in 2001 reflecting a lower average outstanding debt balance in 2002 as compared to 2001.

Income Taxes. We have incurred net operating losses since inception and as a result, we have paid no state or federal income taxes in those years. The state carryforwards are subject to a $2.0 million annual limitation and begin to expire in 2007. The federal carryforwards begin to expire in 2012. 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 2001 and 2002 to fully offset the deferred tax assets.

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. As a result, despite

our annual growth in net revenues, our net revenues in the first quarter of 2003 were lower than the fourth quarter of 2002.

	Quarterly Results								
	2002				2003				2004
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr
	(in thousands, except per share data)								
Net revenues	$ 3,639	$ 4,929	$ 6,851	$ 8,179	$ 7,380	$ 9,205	$11,291	$ 6,244	$ 4,837
Gross margin	907	1,526	2,803	5,457	3,751	4,502	6,689	1,786	1,750
Net loss	(5,413)	(5,587)	(4,964)	(3,410)	(4,470)	(4,704)	(2,212)	(6,418)	(8,084)
Deemed dividend					(4,911)	(152)		(2,815)	
Net loss attributable to common stockholders	$(5,413)	$(5,587)	$(4,964)	$(3,410)	$(9,381)	$(4,856)	$ (2,212)	$(9,233)	$(8,084)
Basic and diluted net loss attributable to common stockholders per share	$ (1.40)	$ (1.45)	$ (1.28)	$ (0.88)	$ (2.43)	$ (1.25)	$ (0.57)	$ (2.39)	$ (2.07)

From the first quarter of 2002 to the third quarter of 2003, we increased our net revenues by an average rate of 22% per quarter from net revenues of $3.6 million to $11.3 million. In the fourth quarter of 2003 and the first quarter of 2004, our net revenues decreased due to our deferral of $5.2 million and $4.5 million of net revenues, respectively, resulting from the pump upgrade program initiated in November 2003. Additionally, our net revenues 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.

Gross margin improved from 25% in the first quarter of 2002 to 59% in the third quarter of 2003. The gross margin for the fourth quarter of 2003 and the first quarter of 2004 dropped to 29%, and 36%, 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.

Net loss before deemed dividend declined from $5.4 million in the first quarter of 2002 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 shipment of pumps for the last three weeks of March 2004.

The deemed dividend was caused by the sale of preferred stock and warrants in January to April and November 2003 (see Note 7 to our consolidated financial statements). 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.

The table below summarizes our issuances of preferred stock and warrants to acquire preferred stock:

Year	Number of Shares	Number of Warrants	Approximate Net Proceeds (in thousands)
2000	1,853,200		$11,077
2001	3,314,355		37,208
2002	581,545		7,235
2003	1,348,624	1,223,762	16,699
	7,097,724	1,223,762	$72,219

Since inception, we have raised an additional $7.7 million through the sale of common stock and the exercise of warrants and options.

In addition, we have funded our operations through lines of credit and long-term debt and lease financing. We have two lines of credit with banks, totaling $6.3 million, of which an aggregate of $4.0 million was outstanding at March 31, 2004. We also have an equipment lease financing loan of $522,000 outstanding at March 31, 2004.

Cash Used in Operating Activities. Cash used in operating activities was, $17.7 million, $21.7 million, and $18.2 million in the years ended December 31, 2001, 2002, and 2003, respectively. The major use of cash was to fund the operating losses of $18.5 million, $19.4 million, and $17.8 million for the years ended December 31, 2001, 2002, and 2003, respectively. Our accounts receivable increased by $1.8 million, $4.6 million, and $7.0 million in 2001, 2002, and 2003, respectively. This increase in accounts receivable resulted from the growth of our business in general. Specific reasons are due to increased sales to Medicare and Medicaid patients, which are traditionally slow payment payors, and to the deferred net revenues generated in the last two months of 2003 ($5.2 million). Additionally, there were proportional increases in other current assets, although these were partially offset by increases in accrued expense and other liabilities. Cash used in operating activities in the three months ended March 31, 2004 was $689,000, which was generated by our net loss offset by changes in working capital, principally deferred revenue, accounts payable, and inventories.

During the year ended December 31, 2003 and the three months ended March 31, 2004, 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 ship the IR 1200 replacement pumps during the second and third quarters of 2004, we will not generate any additional cash due to these upgrade shipments. As a result, in 2004, our cash flows from operating activities will be negatively affected by the replacement activity.

Cash Used in Investing Activities. Cash used in investing activities consisted entirely of capital expenditures of $2.1 million, $2.0 million, and $1.5 million in the years ended December 31, 2001, 2002, and 2003, respectively. Additionally, cash used in investing activities consisted of the purchase of approximately $582,000 of capital expenditures for the three months ended March 31, 2004. 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 $36.0 million, $8.2 million, and $18.9 million in the years ended December 31, 2001, 2002, and 2003, respectively. Additionally, net cash provided by financing activities was $1.4 million for the three months ended March 31, 2004. The net cash provided by financing activities was primarily related to proceeds from sales of equity securities in each of these years and such three month period and as discussed in more detail in

Note 7 to our consolidated financial statements. Cash proceeds from sales of equity securities for the three-year period ended December 31, 2003 were $60.1 million. We received an additional $331,000 from the exercise of options and warrants in the three months ended March 31, 2004. Proceeds from borrowing under lines of credit and the issuance of long-term debt, net of repayments, totaled $2.6 million for the three-year period ended December 31, 2003. Additional net proceeds of $1.3 million from borrowings occurred during the three months ended March 31, 2004. Upon completion of this offering, we plan to repay the borrowings under the outstanding bank lines of credit.

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. The covenant was modified as a result of our deferring certain revenues under SAB 104. Due to the pump deferral program, we were not in compliance with this covenant and certain other covenants under our credit facility as of March 31, 2004. The bank has subsequently waived all such defaults and we are now in compliance with this modified covenant and all other covenants under our credit facility and expect to remain in compliance throughout 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. Borrowings are secured by a pledge of substantially all of our assets. As of March 31, 2004, our outstanding balance on this line of credit was approximately $3.7 million. We also have a $250,000 line of credit with another bank, which is secured by our accounts at such bank. The interest rate on borrowings under this line of credit is at 1.5% above the bank s prime rate. As of March 31, 2004, our outstanding balance on this line of credit was $250,000. Upon completion of this offering, we plan to repay the borrowings under these lines of credit.

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 March 31, 2004, the principal amount outstanding was $522,000.

Operating Leases. At March 31, 2004, commitments related to future lease payments under operating leases, including the lease for our new facility, are $0.9 million in 2004, $1.1 million in 2005, $1.2 million in 2006, $1.2 million in 2007, $1.2 million in 2008, and $6.9 million beyond 2008. There were no material commitments related to future capital expenditures on approved projects at March 31, 2004. At March 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 March 31, 2004, we had cash and cash equivalents of $556,000. We expect to have negative cash flows from operations for most of 2004. We expect increased selling and administrative expenses relating to the promotion of the IR 1200 as well as increased spending for personnel and infrastructure improvement. We believe that the net proceeds from this offering, together with our current cash, lines of credit, and cash generated from our operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into 2005 and the foreseeable future. We are raising $57.0 million in net proceeds from this offering. We anticipate using approximately $11.0 million of the net proceeds for sales and marketing, research and development, expansion, and repayment of debt. The remaining approximately $46.0 million of net proceeds will be used for working capital and general corporate purposes. See Use of Proceeds. If existing cash and 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, 2003. 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	2-3 years	4-5 years	Thereafter	Total
			(in thousands)		
Lease financing:					
Operating lease obligations[1]	$1,068	$2,310	$2,421	$6,937	$12,736
Capital lease obligations	164	187	33		384
Purchase obligations	1,557	2,595			4,152
Lines of credit	2,657				2,657
Letter of credit	550				550
Long-term borrowings:					
Equipment note bank	333	281			614
Total obligations	$6,329	$5,373	$2,454	$6,937	$21,093

(1) The operating lease obligations include leases from the last four months of our old facility lease, as well as all future lease payments for our new facility.

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.

Recent Accounting Pronouncement

In May 2003, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 150 (SFAS 150), Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within the scope of this statement as a liability (or an asset in some circumstances). SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of this standard had no impact on our results of operations or financial position.

Quantitative and Qualitative Disclosures About Market Risk

Market risks related to our operations result primarily from changes in the prime rate of our lenders as the interest rate on our credit facilities is based off the prime rate of or lenders. As of March 31, 2004, we had an aggregate outstanding balance of $4.0 million on our credit facilities. Based on the amount of debt outstanding, and the associated interest rates at March 31, 2004, a 10% increase or decrease in the applicable prime rates would have no material impact on the results of our operations.

Although approximately 7% of our 2003 net revenues and approximately 15% of our net revenues for the three months ended March 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 March 31, 2004, we were not engaged in any foreign currency hedging activities.

BUSINESS

Overview

We design, develop, manufacture, and sell external insulin pumps for people with diabetes. We introduced our first generation pump in July 2000, and 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. 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 March 31, 2004, we shipped over 14,500 pumps, 1.7 million insulin cartridges, and 1.7 million infusion sets. For the year ended December 31, 2003, our net revenues were $34.1 million and $4.8 million for the year ended December 31, 2003 and the three months ended March 31, 2004, respectively.

We estimate that the size of the insulin pump and ancillary supplies market was over $450 million in the United States and over $650 million worldwide in 2003 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 200,000 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 130 full-time sales and clinical personnel located throughout the United States. Our approximate 65-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 65 full-time 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 fifth leading cause of death by disease in the United States. In the United States, diabetes is believed to cost over $132 billion annually in both direct and indirect costs, an estimate that rose 35% from the previous 1997 estimate of $98 billion. 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 stemming 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 160 million people worldwide, approximately 3% of the population, have diabetes. In the United States, approximately 18 million people, over 6% of the population, have diabetes, with about 13 million of these people diagnosed. The number of people in the United States diagnosed with diabetes increased 33% between 1990 and 1998, primarily due to the aging of the population, inappropriate diet, and increasingly sedentary lifestyle. It is estimated that there are approximately 4 million to 5 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 improvements, 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. 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 a range of 47% to 76% for eye disease, approximately 50% for kidney disease, and approximately 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.

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 timing/quantity of meals because of non-peaking insulins	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 sugars in early morning hours) cannot be corrected
Intensive therapy via insulin pump therapy		
No insulin injections-change infusion set every 3 days 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

43

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. Approximately 99% of patients that have started on our pumps have continued on the therapy.

Barriers to Faster Insulin Pump Therapy Adoption

For Provider

Cost of a Pump-start. A pump-start typically requires between 10 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, if any, ranges from approximately $150 to $280 for a pump-start. 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 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 1200, is the smallest full-featured pump on the market. The IR 1200 has a large display, long battery life, precise insulin delivery, and enhanced waterproof integrity.

The thin profile and small size of the IR 1200, 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.

We have limited market experience with our newest product, the IR 1200, as we only started shipping it in April 2004. It is possible that there could be technical or other issues of which we are not yet aware that could impact the acceptance of this product, as well as reduce the net revenues generated by this product in a particular quarter or year.

For Providers

Bridging the Gap. Many providers do not have sufficient resources to conduct a pump-start. Our approximate 65 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.

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 thin and lightweight, designed to be worn under the patients clothing, on a belt, in a pocket, or elsewhere in order not to interfere with normal daily activities. The pump delivers insulin in hundreds of micro-infusions throughout the day utilizing a disposable infusion set and a disposable insulin cartridge. The infusion set consists of plastic tubing that connects to the cartridge and a catheter that

resides in the fat layer underneath the skin. 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.

IR 1200 Insulin Pump. The IR 1200, which weighs approximately 3.2 ounces, is the smallest full-featured pump on the market. The IR 1200 is 25% smaller than our previous generation pump, the IR 1000. We received FDA clearance for the IR 1200 in October 2003 and began shipping the IR 1200 in April 2004. We manufacture this pump, 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 Smart-Bolus interface 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 four 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 2003, as well as for the three months ended March 31, 2004. We provide disposable cartridges and infusion sets to patients. Our cartridge for both the IR 1000 and the IR 1200 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.

Products Under Development

Next Generation Insulin Pumps. Our research and development team is working on several future generations of insulin pumps 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. At this time, we do not know when, if at all, any of our next generation pumps will be commercially available.

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 engineering and market development. We have received 510(k) clearances for earlier designs of our ezSet Infusion Set and Inserter. We will need to review any modifications made subsequent to receipt of our 510(k) clearances to confirm that our new design is still covered by the 510(k) clearances. At this time, we do not know when, if at all, this system will be commercially available.

Continuous Glucose Sensor. Since our inception, we have been developing an implantable continuous glucose sensor, based on technology licensed from Thomas Jefferson University in 1996. 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.

We have conducted various studies to date:

- We took blood samples from a group of over 500 people, with varying medical conditions and using a variety of medications. By measuring and correlating blood glucose using a commercial glucometer and the near infrared spectra of venous blood, we demonstrated that blood glucose can be measured with high accuracy in a diverse population using near-infrared spectroscopy and a universal algorithm.

- We implanted sensor heads in non-diabetic dogs and modulated blood glucose by injecting glucose, insulin, and a hormone to inhibit glucose secretion. By measuring and correlating blood glucose using a commercial glucometer and the near infrared spectra of venous blood, we demonstrated that blood glucose can be measured accurately in dogs on an in-vivo basis using near infrared spectroscopy.

We implanted a mock-up sensor head and Doppler probes in a non-diabetic dog. We measured blood flow on a regular basis and saw no reduction in blood flow. We explanted the sensor head after nine months. The sensor head showed no build up of fibrin or any other tissue.

We evaluated our sensor performance in an ex-vivo setting with 10 people with diabetes over an eight hour period as they went about their normal daily activities such as eating and exercise. We connected a sensor to patients via a catheter for blood sample collection. By measuring and correlating blood glucose using a commercial glucometer and the near infrared spectra of venous blood, we demonstrated that blood glucose can be measured accurately in humans on an ex-vivo basis using near infrared spectroscopy.

We believe that our continuous glucose sensor technology will, if successfully developed, offer advantages over many of the competing or potentially competing products because our sensor technology:

makes a direct measurement in blood rather than in some other body fluid;

directly couples to blood as opposed to having to peer through multiple layers of intervening tissues; and

is not necessarily adversely affected with respect to performance if the sensor becomes coated with encapsulation tissue or a fibrin layer.

Our current sensor research and development activities are supported by two research grants, an R01 grant from the National Institutes of Health and an Advanced Technology Program award from the National Institute of Standards and Technology. The results of the studies discussed above have not been published in peer reviewed medical journals.

Our current development efforts for our continuous glucose sensor are focused on the development of an array of modified light-emitting diodes (LED) emitting light at certain discrete wavelengths within the infrared portion of the electromagnetic spectrum. All animal and human studies performed to date have used an ordinary light bulb producing a continuous spectrum of light from the visible through the infrared, which is too large and too power inefficient for an implantable device. The LED array offers the possibility of miniaturization and low power consumption appropriate for an implantable device. We anticipate that the development project for the LED array will not be completed until at least 2006, if at all. If the LED array is successfully developed, we still have additional development work with respect to packaging and system validation. We do not yet have a detailed plan for this phase.

Our continuous glucose sensor, as described above, would require a PMA. We cannot accurately foresee when we will submit our PMA for this product and/or when this product may be commercially available.

Sales, Clinical Support and Service

United States. We currently have a national sales and support team of over 100 employees. Our sales force consists of approximately 65 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 believe that our strategy of selling through our own direct sales force is an important factor in achieving market penetration and high recurring net revenues. We also sell to durable medical equipment suppliers and distributors who, in turn, sell directly to the patient. Approximately 15% of our domestic pump sales are sold through distributors.

In addition to our sales force, we have approximately 55 full-time and 10 part-time 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 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. On behalf of the patient, we obtain authorization and receive reimbursement by a patient s insurance provider(s) for our pump and disposable supplies. We have over 400 contracts signed with third party payors, including most of the large national payors. 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. We have an internal staff of approximately 30 people who oversee the reimbursement process for pumps and ancillary supplies. We also have over 400 contracts with managed-care companies, including most of the large national payors. 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 patient retention rate for pump supplies is approximately 99%.

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 between training and dosing runs from 10 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 unique in the industry in our ability to provide this program due to our 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 at intervals of two weeks, six weeks, quarterly within the first year, and annually 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 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.

We obtained regulatory approval to market our R1000 and IR 1000 in Canada in March 2001 and July 2002, respectively. In June 2001, we obtained the CE Mark, which permits us to commercially distribute our pumps throughout the European Union. CE is an abbreviation for Conformite Europeene or European Compliance. Since we are self-certifying under the European Union Medical Device Directive (see Manufacturing and Quality Assurance), we may distribute the IR 1200 in the European Union once we complete the requisite testing. 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 moved all of our operations into a new facility located in West Chester, Pennsylvania in May 2004. We must have our quality systems and our new facility reaudited in order to retain the CE mark for our products.

We are presently selling the IR 1000 and ancillary supplies through distributors in Austria, Canada, the Czech Republic, France, Greece, Ireland, Israel, Italy, Spain, Sweden and the United Kingdom and expect to commence selling these products in 2004 in an additional four countries.

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. The following persons are members of our medical advisory board:

Name	Title	Affiliation
Joel Braunstein, MD	Adjunct Assistant Professor of Medicine, Division of Cardiology	Johns Hopkins University
Robert H. Creech, MD	Director	Diabetes Wellness Center
Steve Edelman, MD	Associate Professor of Medicine Diabetes and Endocrinology	University of California San Diego, VA San Diego Healthcare System
Satish Garg, MD	Professor of Medicine and Pediatrics and Director of Adult Diabetes Program	Barbara Davis Center for Childhood Diabetes
Barry J. Goldstein, MD	Director, Division of Endocrinology, Diabetes and Metabolic Diseases; Professor, Biochemistry and Molecular Pharmacology	Thomas Jefferson University
Noel Keith Maclaren, MD	Professor Department of Pediatrics; Director, Cornell Juvenile Diabetes Program	Weill Medical College of Cornell University
Martha S. Nolte, MD	Associate Clinical Professor of Medicine; Director, Clinical Diabetes Center	University of California, San Fransico
Henry Rodriguez, MD	Assistant Professor of Clinical Pediatrics; Director, Pediatric Diabetes Clinical Program	Indiana University Riley Hospital for Children
Alan B. Schorr, DO	Clinical Instructor Philadelphia College of Osteopathic Medicine	Private Practice
David Sutton, MD	Vice President	Northeast Florida Endocrine and Diabetes Associates
Jay Skyler, MD	Director	Diabetes Research Center
Howard A. Wolpert, MD	Medical Director, Insulin Pump Program	Joslin Diabetes Center

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 55 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.

We received approval from TUV America Inc., a Notified Body to the International Standards Organization (ISO) quality system standards, that allows us to self-certify our existing product families into countries of the European Union based on annual certification of our quality system. These approvals are to ISO 9001 and ISO 13485 standards that include design control requirements.

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 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 April 30, 2004, we had obtained six issued United States patents, and had ten 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 two foreign patents and have filed 14 foreign patent applications in six foreign patent offices seeking rights corresponding to aspects of our issued United States patents and pending United States patent applications.

As of April 30, 2004, we had registered the trademarks ANIMAS and EZ MANAGER with the United States Patent and Trademark Office on the Principal Register. We have applied with the United States Patent and Trademark Office to register the trademarks EZ SET, ezBolus, and CHAMPION, and the first two of these applications have been published for opposition. We use the

trademarks Carb Smart™, ezWrap™, ezBG™, ezFlex Programming™, ezFlip™, PrimeSmart™, Carb Smart Plus™, and ezView™ in connection with our business.

In addition to developing our own technology, we have entered into several license agreements with several vendors who are developing various components of our continuous glucose sensor. We have exclusive worldwide licenses to patents and other intellectual property from Thomas Jefferson University developed by Dr. Jeffrey Joseph, a professor of anesthesiology, and his collaborators. These licenses grant us the right to use the licensed patents to make, use, and sell continuous optical sensors that contain the licensed technology. We pay for these licenses through a combination of fixed payments and royalties on sales of covered products. Each of these licenses continues until expiration of the licensed patents.

Research and Development

Our research and development efforts focus on developing further enhancements to the IR 1200 pump, future generation pumps, infusion sets, and our continuous glucose sensor. Our research and development staff consists of approximately 30 people, including two 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.

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 has the majority 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 during 2004.

Continuous monitoring or sensing is a very competitive field. To date, the FDA has approved, for very limited applications, three continuous monitors or sensors, two by Medtronic, the CGMS System Gold and Guardian System, and one by Cygnus, the GlucoWatch. All of these products have limited capabilities, and none of them is labeled as a substitute for current blood glucose testing where patients need to draw blood. It is not yet known when the Guardian System will become available commercially, as it received FDA approval in February 2004. The Guardian System is being promoted as a system to detect dangerously low blood glucose measurements. It requires at least two finger-stick tests of blood glucose a day to calibrate it. Only the Medtronic CGMS system and the Cygnus GlucoWatch are currently in commercial use. The CGMS system 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. 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 has submitted a real-time continuous monitor or

sensor to the FDA and we believe that others will be submitted to the FDA before we submit ours. It is unknown when, if ever, any continuous monitor or sensor will be approved as a substitute for current glucose monitors or sensors.

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 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 continuous glucose sensor under development 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 inspected our facility for QSR compliance. On March 24, 2004, the FDA issued a Form FDA 483 setting forth a series of written inspectional observations of alleged QSR deviations pertaining to our R1000 and IR 1000 pumps. 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 an allegation that we have not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of our organization. The FDA investigator observed instances in which we have not adequately documented and evaluated complaints, have not conducted adequate failure investigations to determine the root cause of the complaints, and have not adequately evaluated whether appropriate corrective actions should be implemented to minimize potential risks to patients. The observations also alleged that we have not adequately established and/or followed procedures relating to various activities such as document control, product and equipment testing, software validation and employee training.

On April 14, 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. The FDA is likely to conduct a reinspection of our facility to verify that we have corrected the alleged deviations. We will also need to make sure that our new facility meets applicable FDA requirements. 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. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In June 2001, TUV Product Service GmbH, a Notified Body under the European Union Medical Device Directive, certified our R1000 pump, which allowed the CE conformity marking to be applied.

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 2004, we expect to apply for the Medical Device License for the

IR 1200 to allow us to market it in Canada. We also expect to seek approval for our IR 1200 in Israel, Australia, and New Zealand during 2004.

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:

- 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 with 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.

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 30 people to simplify and expedite claims processing and to assist patients in obtaining third party reimbursement. We believe that more than 90% 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.

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 April 30, 2004, we had 290 full-time employees, including 90 in field sales and sales administration, seven in marketing, 80 in clinical, 45 in operations and manufacturing, 31 in engineering and research and development, 10 in quality assurance, and 34 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.

Facilities

We have a 10-year lease expiring in 2014 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.

Legal Proceedings

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

MANAGEMENT

Executive Officers and Directors

The following table sets forth information concerning our executive officers and directors as of April 30, 2004:

Name	Age	Position
Katherine D. Crothall	55	Founder, President, Chief Executive Officer and Director
Richard Baron	48	Vice President-Finance and Chief Financial Officer
Audrey Finkelstein	53	Executive Vice President-Marketing, Sales and Clinical
James McGee	45	Vice President, Sales
John Holly	55	Vice President, Operations
Patrick Paul	51	Vice President, Engineering
Richard Michelin	56	Vice President, Quality and Regulatory Affairs
Edward Cahill[(1)]	51	Director
Graeme Crothall	65	Director
William A. Graham IV	63	Director
David Joseph[(2)(3)]	61	Director
John J. McDonough[(1)(3)]	67	