

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.**

	<u>Per Share</u>	<u>Total</u>
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.

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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.

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## 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](http://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<sup>TM</sup>, ezWrap<sup>TM</sup>, ezBG<sup>TM</sup>, ezFlex Programming<sup>TM</sup>, ezFlip<sup>TM</sup>, PrimeSmart<sup>TM</sup>, Carb Smart Plus<sup>TM</sup>, and ezView<sup>TM</sup> 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)					
<b>Statement of Operations Data:</b>					
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) <sup>(2)</sup>	(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) <sup>(3)</sup>		\$ (0.58) <sup>(3)</sup>

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Unaudited pro forma  
weighted average shares  
outstanding basic and  
diluted

12,889,179(3)

13,979,299(3)

	As of December 31,			As of
	2001	2002	2003	March 31, 2004
(in thousands)				
<b>Balance Sheet Data:</b>				
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
	<hr/>
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
	<hr/>
Adjusted pro forma net tangible book value per share after this offering	3.08
	<hr/>
Dilution per share to new investors	\$ 11.92
	<hr/>

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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
<b>Total</b>	<b>18,531,753</b>	<b>100.0%</b>	<b>\$ 145,888,000</b>	<b>100.0%</b>	

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
<b>Total</b>	<b>21,249,761</b>	<b>100.0%</b>	<b>\$ 164,716,000</b>	<b>100.0%</b>	

## 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)							
<b>Statement of Operations Data:</b>							
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) <sup>(2)</sup>	(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)

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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
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Unaudited pro forma basic and diluted net loss attributable to common stockholders per share					\$ (1.99) <sup>(3)</sup>		\$ (0.58) <sup>(3)</sup>
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Unaudited pro forma weighted average shares outstanding basic and diluted					12,889,179(3)		13,979,299(3)
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As of December 31,

	1999	2000	2001	2002	2003	As of March 31, 2004
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(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)						
<b>Consolidated Statements of Operations</b>						
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%
<b>Net Revenues, Cost of Products Sold and Gross Margin</b>						
<b>Net Revenues</b>						
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)%
<b>Cost of Products Sold</b>						
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)%
<b>Gross Margin</b>						
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)%
<b>Gross Margin %</b>						
Insulin pumps		62.6%		16.0%		

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Ancillary supplies	26.8%	42.6%
	<hr/>	<hr/>
Total	50.8%	36.2%
	<hr/>	<hr/>

**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)						
<b>Consolidated Statements of Operations</b>						
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%
<b>Net Revenues, Cost of Products Sold and Gross Margin</b>						
<b>Net Revenues</b>						
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%
<b>Cost of Products Sold</b>						
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%
<b>Gross Margin</b>						
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%
<b>Gross Margin %</b>						

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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).

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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)						
<b>Consolidated Statements of Operations</b>						
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%
<b>Net Revenues, Cost of Products Sold and Gross Margin</b>						
<b>Net Revenues</b>						
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%
<b>Cost of Products Sold</b>						
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%
<b>Gross Margin</b>						
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%
<b>Gross Margin %</b>						
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

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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.

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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
	<u>7,097,724</u>	<u>1,223,762</u>	<u>\$72,219</u>

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

	<u>Less than 1 year</u>	<u>2-3 years</u>	<u>4-5 years</u>	<u>Thereafter</u>	<u>Total</u>
(in thousands)					
Lease financing:					
Operating lease obligations <sup>(1)</sup>	\$ 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
<b>Total obligations</b>	<b>\$ 6,329</b>	<b>\$ 5,373</b>	<b>\$ 2,454</b>	<b>\$ 6,937</b>	<b>\$ 21,093</b>

(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 our 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.

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

Type of therapy	Advantages	Disadvantages
<p><b>Conventional therapy</b> 1 to 2 shots of insulin per day, typically a mixture of a long-acting and regular insulin, both of which exhibit insulin peaking</p>	<p>Easiest for healthcare professionals to teach</p> <p>Requires little cognitive ability on the part of the patient</p> <p>Lowest cost of supplies (insulin, syringes, etc.) of all therapies</p>	<p>Least physiologic approach</p> <p>Highest long-term complication rates</p> <p>Lowest quality of life</p> <p>Many hypoglycemic and hyperglycemic events roller coaster effect in blood glucose is common</p> <p>Variation in insulin absorption is common</p> <p>Limited lifestyle flexibility meals need to be timed to insulin peak</p>
<p><b>Intensive therapy: MDI with traditional insulins</b> 2 shots per day of a mixture of long-acting and regular insulin, both of which exhibit insulin peaking</p> <p>-plus -</p> <p>1 to 2 shots of a rapid- acting insulin (before all meals and snacks)</p>	<p>Less complicated regimen than pump therapy</p> <p>Fewer long-term complications than with conventional therapy</p>	<p>Frequent shots (as many as 6 per day are not unusual)</p> <p>Many hypoglycemic and hyperglycemic events roller coaster effect in blood glucose is still common</p> <p>Variation in insulin absorption is common</p> <p>Limited lifestyle flexibility meals need to be timed to insulin peak</p>
<p><b>Intensive therapy: MDI with analog insulins</b> 1 to 2 shots per day of long-acting basal insulin (such as Lantus)</p> <p>-plus -</p> <p>3 to 4 shots of insulin (before all meals and snacks)</p>	<p>Less complicated regimen than pump therapy</p> <p>Fewer long-term complications than conventional therapy</p> <p>Less hypoglycemia than with traditional insulins</p> <p>Can better accommodate changes to timing/quantity of meals because of non-peaking insulins</p>	<p>Frequent shots (as many as six per day are not unusual)</p> <p>Roller coaster effect in blood glucose still occurs</p> <p>Lantus cannot be mixed with other insulins</p> <p>Dawn phenomenon (high blood sugars in early morning hours) cannot be corrected</p>
<p><b>Intensive therapy via insulin pump therapy</b> No insulin injections-change infusion set every 3 days on average</p>	<p>Most physiologic approach</p> <p>Best control of blood glucose fewer long term complications</p> <p>Highest quality of life</p> <p>Enables most flexible lifestyle</p> <p>Insulin delivered discreetly and easily</p>	<p>Most complex approach of all insulin therapies to teach and learn</p> <p>Significant glucose monitoring required</p> <p>Highest upfront cost of all insulin therapies</p>



## 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

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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 Francisco
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 Diagnostics, 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 Diagnostics has the leading market share of the insulin pump market in Europe. Roche Diagnostics is currently prohibited by the FDA from selling its infusion pumps in the United States. We anticipate that Roche Diagnostics 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 <sup>(1)</sup>	51	Director
Graeme Crothall	65	Director
William A. Graham IV	63	Director
David Joseph <sup>(2)(3)</sup>	61	Director
John J. McDonough <sup>(1)(3)</sup>	67	Director
Thomas Morse <sup>(1)(2)</sup>	52	Director
A. Peter Parsons <sup>(2)(3)</sup>	58	Director

(1) Member of our audit committee

(2) Member of our compensation committee

(3) Member of our governance and nominating committee

*Katherine D. Crothall* founded Animas Corporation in 1996 and has served as our President, Chief Executive Officer and Chairman of the Board since 1996. From October 1988 to September 1993, Ms. Crothall was President and Chief Executive Officer of Luxar Corporation. Luxar, which she founded in 1988, sold and manufactured CO<sub>2</sub> lasers for cosmetic, oral, surgical, dental, dermatological, and surgical applications. Ms. Crothall also founded and was President of Laakmann Electro-Optics, which manufactured and marketed CO<sub>2</sub> lasers, and was sold to Johnson & Johnson in 1981. Ms. Crothall holds a B.S. in Electrical Engineering from the University of Pennsylvania and a Ph.D. in Electrical Engineering from the University of Southern California.

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

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

*James McGee* has served as our Vice President, Sales since June 2003. From February 1997 to March 2003, Mr. McGee held various positions with Medtronic MiniMed, a division of Medtronic, Inc., a

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provider of insulin pump therapy, including Vice President of Sales and Marketing (Home Medical Supplies), Director of Managed Care and Vice President of Patient Services. Mr. McGee holds a B.S. in Biology from the University of Central Florida.

*John Holly* has served as our Vice President, Operations since August 2000. From February 2000 to July 2000, Mr. Holly was self-employed as a consultant and was researching business opportunities for acquisition. From June 1998 to January 2000, Mr. Holly was Vice President of Operations at Clinicon Corporation, a manufacturer of a diamond scalpel and CO<sub>2</sub> laser for use in fine cosmetic surgery. From November 1990 to June 1998, Mr. Holly was Vice President Operations at Luxar Corporation. Mr. Holly holds a B.S. in Industrial Engineering from Queens University, Belfast, Ireland.

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

*Richard Michelin* has served as our Vice President, Quality and Regulatory Affairs since September 2001. From April 1998 to August 2001, Mr. Michelin was Vice President of Quality and Regulatory Affairs at Hi-tronics Designs, Inc., a contract designer and manufacturer of class III medical devices. He served as Senior Director from January 1998 until his promotion in April 1998. From July 1985 to December 1997, Mr. Michelin was Director of Quality and Material Control for Electro-Biology, Inc., that designed and manufactured implantable and non-implantable medical devices. Mr. Michelin holds a B.S. in Electrical Engineering from the University of New Hampshire and a M.B.A. from Long Island University.

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

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

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



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

*John J. McDonough* has served as a member of our board of directors since March 2002 and is the chairman of our audit committee. Mr. McDonough co-founded and has been Chairman of McDonough Medical Products Corporation, which manufactures, markets, and supplies medical and dental imaging devices, since June 2001. Mr. McDonough served as Vice Chairman and Chief Executive Officer of Newell Rubbermaid Inc. from January 1998 through December 2000. Prior to that, Mr. McDonough was Chairman and Chief Executive Officer of GENDEX Corporation, which he founded in April 1983, until it merged with DENTSPLY, a manufacturer of dental supplies and equipment for the worldwide dental market, in June 1993. He was Vice Chairman and Chief Executive Officer of DENTSPLY International Inc. until February 1995, then served as Vice Chairman of DENTSPLY through October 1995. Mr. McDonough graduated with honors from the University of Notre Dame, and is a certified public accountant.

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

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

#### **Executive Officers**

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

#### **Board of Directors**

Upon closing of this offering, our board of directors will be divided into three classes of directors, each containing, as nearly as possible, an equal number of directors. Directors within each class are elected to serve three-year terms and approximately one-third of the directors sit for election at each annual meeting of our stockholders. The terms of Graeme Crothall, David Joseph and A. Peter Parsons will expire in 2005, the terms of John J. McDonough and Edward Cahill will expire in 2006 and the terms of Katherine D. Crothall, William A. Graham IV, and Thomas Morse will expire in 2007. A classified board of directors may have the effect of deterring or delaying any attempt by any person or group to obtain control of us by a proxy contest since such third party would be required to have its nominees elected at two separate annual meetings of our stockholders in order to elect a majority of the members of our board of

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

### **Board Committees**

Our board of directors has an audit committee, a compensation committee, and a governance and nominating committee, each of which has the composition and responsibilities described below.

#### **Audit Committee**

Our audit committee oversees our corporate accounting and financial reporting process. Our audit committee:

evaluates the qualifications, independence, and performance of our independent auditors;

determines the engagement of our independent auditors;

approves the retention of our independent auditors to perform any proposed permissible non-audit services;

monitors the rotation of the partners of our independent auditors on our engagement team as required by law;

reviews our systems of internal controls established for finance, accounting, legal compliance, and ethics;

reviews our accounting and financial reporting processes;

provides for effective communication between our board of directors, our senior and financial management, and our independent auditors;

discusses with management and our independent auditors the results of our annual audit and the review of our quarterly financial statements;

reviews the audits of our financial statements; and

implements a pre-approval policy for certain audit and non-audit services performed by our independent auditors.

The current members of our audit committee are John J. McDonough, Thomas Morse, and Edward Cahill, each of whom is a non-management member of our board of directors. John J. McDonough is our audit committee financial expert (as is currently defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002). We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, The NASDAQ National Market, and SEC rules and regulations, including those regarding the independence of our committee members. We intend to comply with future requirements to the extent they become applicable to us.

#### **Compensation Committee**

Our compensation committee reviews and recommends policies relating to the compensation and the benefits of our officers and employees. Our compensation committee:

reviews and approves corporate goals and objectives relevant to the compensation and the benefits of our President and Chief Executive Officer and our other executive officers;

evaluates the performance of these officers in light of those goals and objectives; and

sets compensation of these officers based on such evaluations.

Our compensation committee also administers the issuance of stock options and other awards under our 2004 Equity Incentive Plan, 1998 Equity Compensation Plan, and 1996 Incentive Stock Plan. The current members of our compensation committee are Thomas Morse, A. Peter Parsons, and David Joseph, each of whom is a non-management member of our board of directors. We believe that the composition and functioning of our compensation committee complies with all applicable requirements of The NASDAQ National Market, including those regarding the independence of our committee members. We intend to comply with future requirements to the extent they become applicable to us.

#### **Governance and Nominating Committee**

Our governance and nominating committee oversees all aspects of our corporate governance functions. The committee makes recommendations to our board of directors regarding director candidates and assists our board of directors in determining the composition of our board of directors and its committees. The current members of our governance and nominating committee are John J. McDonough, David Joseph, and A. Peter Parsons, each of whom is a non-management member of our board of directors. We believe that the composition of our governance and nominating committee complies with all applicable requirements of The NASDAQ National Market, including those regarding the independence of our committee members. We intend to comply with future requirements to the extent they become applicable to us.

#### **Compensation Committee Interlocks and Insider Participation**

Prior to establishing our compensation committee, our board of directors as a whole performed the functions delegated to our compensation committee. No member of our compensation committee or any of our executive officers has a relationship that would constitute an interlocking relationship with executive officers or directors of another entity. None of our officers or employees is a member of our compensation committee.

#### **Director Compensation**

**Board of Directors.** Each of our non-employee directors will receive an option to purchase 10,000 shares of our common stock upon initial election to our board of directors at one of our annual meetings. If a non-employee director is initially elected to our board of directors at any time other than an annual meeting, the number of shares of his or her initial option award will be reduced pro-rata to reflect his or her service during the period between the date that he or she is first elected to our board of directors and the date of our next annual meeting. In addition, non-employee directors will receive an additional option to purchase 10,000 shares of our common stock on the earlier of the date of our annual meeting or July 1st of each year for each successive year that such non-employee director serves on our board of directors.

In December 2003, each of our existing non-employee directors received two options to purchase 5,334 shares of our common stock with one option vesting quarterly during calendar year 2004 and the other option vesting quarterly during calendar year 2005. In order to transition to our new non-employee director compensation program, each of our existing non-employee directors will receive an additional option to purchase 4,667 shares of our common stock upon the closing of this offering. In addition, if an existing non-employee director is re-elected to our board of directors at our 2005 annual meeting, such non-employee director will receive an additional option to purchase 7,334 shares of our common stock at our 2005 annual meeting, of which 2,334 shares will vest quarterly during the period from the date of grant through December 2005 and the remaining 5,000 shares will vest quarterly during the period from January 2006 through June 2006.

*Committees of Our Board of Directors.* Upon the closing of this offering and at each annual meeting thereafter:

each member of our audit committee will receive an option to purchase 1,250 shares of our common stock and the chairman of our audit committee will receive an additional option to purchase 625 shares of our common stock; and

each member of our compensation and our governance and nominating committees will receive an option to purchase 750 shares of our common stock and the chairmen of each of these committees will receive an additional option to purchase 375 shares of our common shares.

If a non-employee director joins a committee or becomes chairman of a committee at any time other than within the forty-five day period following the date of one of our annual meetings, his or her option award for committee service will be pro-rated for the period between the date that he or she is elected and the date of our next annual meeting.

All stock options to non-employee directors will have an exercise price equal to the fair market value of our common stock on the date of grant, which for those options granted on the closing of this offering will be our initial public offering price per share. Non-employee director options will vest quarterly over the one-year period following the date of grant and will automatically become fully vested and exercisable on the date of a change of control.

Our non-employee directors are also reimbursed for out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors and our committees of our board of directors. Any director who is also our employee will receive no compensation for service as a member of our board of directors or any of our committees of our board of directors.

**Executive Compensation**

The following table sets forth summary information concerning compensation of our President and Chief Executive Officer and each of the next four most highly compensated current executive officers whose total annual salary and bonus exceeded \$100,000 during the fiscal year ended December 31, 2003. We refer to these persons as our named executive officers.

**Summary Compensation Table**

Name and Principal Position	Annual Compensation			Long Term Compensation Awards	All Other Compensation (\$)
	Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Securities Underlying Options (#)	
Katherine D. Crothall President and Chief Executive Officer	250,000	55,000			
Richard Baron Vice President-Finance and Chief Financial Officer	205,200	42,500			
Audrey Finkelstein Executive Vice President-Marketing, Sales and Clinical	162,000	37,500		40,000	
John Holly Vice President, Operations	149,800	32,500		13,334	
Patrick Paul Vice President, Engineering	155,366	15,000	55,208(1)	13,334	

(1) Consists of relocation expenses.

**Option Grants in Last Fiscal Year**

The following table sets forth the stock options granted to each named executive officer during 2003, including the potential realizable value over the 10-year term of the options, based on assumed rates of stock appreciation of 5% and 10%, compounded annually. These assumed rates of appreciation comply with the rules of the SEC and do not represent our estimate of future stock price. Actual gains, if any, on stock option exercises depend on the future performance of our common stock.

In 2003, we granted options to purchase up to an aggregate of 342,115 shares to employees, directors, and consultants. All options were granted under our 1998 Equity Compensation Plan. The vesting period for these options ranges from immediate vesting to five years.

## Option Grants in 2003

Name	Number of Securities Underlying Options Granted (#)	Percent of Total Options Granted to Employees	Exercise Price Per Share(\$)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for 10-Year Option Term(\$)	
					5%	10%
Katherine D. Crothall						
Richard Baron						
Audrey Finkelstein	40,000	11.7%	15.00	12/31/13	377,400	956,400
John Holly	13,334	3.9%	15.00	12/31/13	125,806	318,816
Patrick Paul	13,334	3.9%	15.00	12/31/13	125,806	318,816

## Aggregate Option Exercises in 2003 and Option Values

The following table sets forth information concerning the number and value of unexercised options held by each of our named executive officers on December 31, 2003. The value realized and the value of unexercised in-the-money options at December 31, 2003 are based on the initial public offering price of \$15.00 per share, less the per share exercise price, multiplied by the number of shares issued or issuable, as the case may be, upon exercise of the option. The weighted average exercise price of outstanding options for the table below is \$8.41.

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options at December 31, 2003 (#)		Value of Unexercised in-the-Money Options at December 31, 2003 (\$)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Katherine D. Crothall	56,833	783,945	36,000	144,000	202,500	810,000
Richard Baron	21,333	198,667	30,933	49,067	299,000	426,000
Audrey Finkelstein			92,667	64,000	931,250	165,000
John Holly			27,067	41,600	215,250	201,000
Patrick Paul			17,333	41,333	128,500	204,000

## Employee Benefit Plans

## 2004 Equity Incentive Plan

Our 2004 Equity Incentive Plan (2004 Plan) will become effective upon the closing of this offering. Our 2004 Plan provides for the award of:

- restricted shares of our common stock;
- restricted units of our common stock;
- incentive stock options;
- non-qualified stock options; and
- stock appreciation rights.

Grants can be made to our employees, directors, consultants, and other individuals who perform services for us.

**Number of Shares of Our Common Stock Available under Our 2004 Plan.** We have reserved a total of 3,900,405 shares of our common stock for issuance pursuant to our 2004 Plan plus any shares returned to our 1998 Equity Compensation Plan (1998 Plan) and 1996 Incentive Stock Plan (1996 Plan) as a result of termination of options. As of April 30, 2004, options to purchase an aggregate of 2,580,434 shares of our common stock were outstanding under our 1998 Plan and our 1996 Plan. Awards of stock options or stock appreciation rights under our 2004 Plan are limited to 500,000 shares of our common stock per participant in any calendar year. Shares subject to forfeited, cancelled, or expired awards become available for grant again under our 2004 Plan. In addition, shares withheld in payment of any exercise price or in satisfaction of any withholding obligation arising in connection with an award granted under our 2004 Plan become available for grant again under our 2004 Plan.

**Administration of Our 2004 Plan.** Our compensation committee administers our 2004 Plan. Under the terms of our 2004 Plan, our compensation committee must consist of two or more directors. Our compensation committee interprets our 2004 Plan, selects award recipients, determines the number of shares subject to each award, and establishes the price, vesting, and other terms of each award.

While there are no predetermined performance formulas or measures or other specific criteria used to determine recipients of awards under our 2004 Plan, awards are based generally upon:

- consideration of the grantee's position and responsibilities;
- the nature of services provided;
- the value of the services to us;
- the present and potential contribution of the grantee to our success;
- the anticipated number of years of service remaining; and
- other factors which our compensation committee deems relevant.

Our 2004 Plan has no specified term, although incentive stock options will not be granted more than 10 years after the adoption of our 2004 Plan.

**Restricted Shares under Our 2004 Plan.** Restricted shares are shares of our common stock issued to an employee that will be forfeited to us if certain vesting conditions established by our compensation committee at the time of grant (such as a specified period of continued employment or the fulfillment of specified individual or corporate performance goals) are not met. Restricted shares may be sold under our 2004 Plan (at its full value or at a discount) or may be granted solely in consideration for services.

Upon or in anticipation of our change of control, our compensation committee may:

- cause restrictions on shares of restricted stock to lapse;
- cancel restricted stock in exchange for shares of restricted stock of a successor corporation; or
- redeem restricted stock for cash or other substitute consideration.

**Restricted Share Units under Our 2004 Plan.** Our 2004 Plan also provides for the grant of restricted share units. A restricted share unit entitles its holder to a cash payment equal to the fair market value of

one share of our common stock on the date of payment. Restricted share units will be forfeited to us if certain vesting conditions established by our compensation committee at the time of grant (such as a specified period of continued employment or the fulfillment of specified individual or corporate performance goals) are not met prior to the date of payment.

Upon or in anticipation of our change of control, our compensation committee may:

- remove any forfeiture conditions on the outstanding restricted share units;
- cancel outstanding restricted share units in exchange for restricted share units of a successor corporation; or
- redeem outstanding restricted share units for cash or other substitute consideration.

**Stock Options under Our 2004 Plan.** Our 2004 Plan permits the grant of incentive stock options to our employees and the employees of our subsidiaries. Our 2004 Plan also provides for the grant of non-qualified stock options to our employees, directors, consultants, and other individuals who perform services for us (as well as to employees, directors, consultants, and service providers of our subsidiaries). The exercise price of any incentive stock options granted under our 2004 Plan may not be less than 100% of the fair market value of our common stock on the date of grant. Options granted under our 2004 Plan may be exercised for cash or in exchange for shares of our common stock owned by the option holder for more than six months having a fair market value on the date of exercise equal to the option exercise price.

Under our 2004 Plan, each option is exercisable at such time and to such extent as specified in the pertinent option agreement between us and the option recipient. However, no award shall be exercisable with respect to any shares of our common stock later than 10 years after the date of such award. Unless otherwise specified by our compensation committee with respect to a particular option, all options are non-transferable, except upon death.

Upon our change of control, our compensation committee may:

- cause outstanding options to become immediately and fully exercisable;
- require that the grantees surrender their outstanding options in exchange for a payment by us of an amount equal to the amount by which the fair market value of the shares of stock subject to the option exceeds the option exercise price; or
- after giving grantees an opportunity to exercise their outstanding options, terminate any or all outstanding options at such time as our board of directors deems appropriate.

**Stock Appreciation Rights under Our 2004 Plan.** Our 2004 Plan also provides for the grant of stock appreciation rights. A stock appreciation right entitles its holder to a cash payment of the excess of the fair market value of our common stock on the date of exercise, over the fair market value of our common stock on the date of grant. No stock appreciation right issued under our 2004 Plan will have a term of more than 10 years.

Upon or in anticipation of our change of control, our compensation committee may:

- cause outstanding stock appreciation rights to become immediately exercisable; or
- provide for the cancellation of outstanding stock appreciation rights in exchange for cash and/or other substitute consideration.



### **1998 Equity Compensation Plan and 1996 Incentive Stock Plan**

Although we maintain our 1998 Plan and 1996 Plan, we will not make any additional grants under such plans following the closing of this offering. As of April 30, 2004, options to purchase an aggregate of 2,580,434 shares of our common stock were outstanding under such plans at exercise prices ranging from \$0.75 to the initial public offering price. Of the options outstanding, 1,583,703 have vested as of the date of the prospectus.

Participation in our 1998 Plan and our 1996 Plan was limited to our employees, officers, directors, and consultants or those of any of our affiliates. Although awards under our 1998 Plan and the 1996 Plan could have been in the form of incentive stock options, non-qualified stock options, stock appreciation rights, or stock awards, we did not award any stock appreciation rights or stock awards. Stock option grants under our 1998 Plan and 1996 Plan are not transferable by the participants, except upon death. Stock options may not be exercised more than 10 years after the date of grant. In the event of our change of control, all options granted under our 1996 Plan will become vested and fully exercisable. Under the 1998 Plan, in the event of our change of control, our board of directors may: (i) cause outstanding options to become immediately and fully exercisable, (ii) require that the option holders surrender their outstanding options in exchange for a payment equal to the amount by which the fair market value of the shares of stock subject to the option exceeds the option exercise price, or (iii) after giving option holders an opportunity to exercise their outstanding options, terminate any or all outstanding options at such time as our board of directors deems appropriate. The exercise price of stock options granted under our 1998 Plan and 1996 Plan may be paid in cash or by tender of previously acquired shares of our common stock.

### **2004 Employee Stock Purchase Plan**

Our 2004 Employee Stock Purchase Plan (Stock Purchase Plan) will become effective upon the closing of this offering. Our Stock Purchase Plan generally allows substantially all of our full-time employees who have been employed by us for at least 30 days to purchase shares of our common stock at a discount from the prevailing market price at the time of purchase. These shares are either issued directly by us or purchased on the open market. Any employee owning (or having a right to acquire) five percent or more of our voting power or value is not eligible to participate in our Stock Purchase Plan. An aggregate of 500,000 shares of our common stock will be available for purchase under our Stock Purchase Plan. Any future increase in the number of shares of our common stock subject to our Stock Purchase Plan will require stockholder approval.

Offerings under our Stock Purchase Plan are expected to begin on each July 1st and January 1st following this offering. Each offering is expected to be six months long, so that offerings under our Stock Purchase Plan will not overlap. Each offering will include one six-month purchase period, ending on each December 31st and June 30th.

Once enrolled in a specific offering, an eligible employee will be able to specify an amount (not greater than 10% of pay) to be withheld from his or her paycheck and credited to a bookkeeping account established for him or her (Participation Account). Amounts in the Participation Account will be applied to the purchase of shares of our common stock on the last day of each purchase period. The price of such shares will be equal to 85% of the lesser of: (i) the price of our common stock on the last day of the purchase period, or (ii) the price of our shares on the first day of the offering period (or, for purposes of the first offering, the initial public offering price).

No employee may purchase more than \$25,000 worth of our common stock (determined based on the price on the first day of the offering period) in any calendar year under our Stock Purchase Plan (and any other employee stock purchase plans later established by us or our subsidiaries).

If we merge or consolidate with another company, if we sell substantially all our assets, or if we liquidate or dissolve, the end of the then-current purchase period will be accelerated and shares will be purchased

under our Stock Purchase Plan immediately before the merger, consolidation, asset sale, liquidation or dissolution (unless our Stock Purchase Plan is assumed by a successor entity).

A committee appointed by our board of directors will administer our Stock Purchase Plan. Our board of directors may amend or terminate our Stock Purchase Plan. Our Stock Purchase Plan is intended to comply with the requirements of Section 423 of the Internal Revenue Code of 1986, as amended (Internal Revenue Code). Our board of directors may terminate our Stock Purchase Plan at any time.

#### **401(k) Plan**

We maintain our Retirement Savings Plan (401(k) Plan) for the benefit of our eligible employees. Our 401(k) Plan is intended to be qualified under section 401(a) of the Internal Revenue Code and consists of a 401(k) component, a discretionary 401(m) matching component and a discretionary profit-sharing component. Employees eligible to participate in our 401(k) Plan are those employees who have completed at least 30 days of service and attained the age of 18. Under the 401(k) component, participants may elect to defer between 1% and 90% of their eligible compensation each year up to the maximum permitted by the Internal Revenue Code. Under the 401(m) matching component, we may match each participant's elective deferrals in amounts to be determined by us in our sole discretion. Under the profit-sharing component, we may make additional contributions in amounts to be determined by us in our sole discretion. Any profit-sharing contributions are allocated to an eligible participant based on the ratio of his or her annual compensation to the aggregate annual compensation of all eligible participants. Matching contributions and profit-sharing contributions vest ratably over six years, or earlier upon the participant's attainment of the appropriate retirement age, retirement for disability, or death, or upon termination of our 401(k) Plan. All assets of our 401(k) Plan are currently invested, subject to participant-directed elections, in a variety of mutual funds chosen from time to time by us. Payments of 401(k) Plan benefits are made in cash in the form of a single lump sum. Distribution of a participant's vested interest generally occurs upon termination of employment (including by reason of retirement, death or disability).

#### **Employment Arrangements**

***Katherine D. Crothall.*** An amended employment agreement with Ms. Crothall, who serves as our President and Chief Executive Officer, will become effective upon the closing of this offering. The agreement has an initial term that expires on January 1, 2005. The agreement will continue for successive one-year periods unless either party provides notice to terminate. If a change of control occurs prior to January 1, 2005, the earliest the agreement will terminate is the second anniversary of the change of control. Ms. Crothall receives an annual base salary of \$285,000, subject to increases upon an annual review by our board of directors. Ms. Crothall is permitted to participate in any short-term or long-term incentive compensation programs that we may establish for our senior level officers generally. Any payment under a short-term or long-term program will be based on Ms. Crothall's performance and our business results as determined by our board of directors. Ms. Crothall also receives certain additional benefits (beyond those generally available to our employees) including an automobile allowance and additional life insurance.

Either Ms. Crothall or we may terminate her employment at any time, subject to certain severance payments and other benefits depending on the reason for such termination. If we terminate Ms. Crothall's employment for cause or she voluntarily terminates her employment without good reason, Ms. Crothall will receive only those benefits required to be provided to Ms. Crothall by the terms of any of our applicable benefit plans. If, however, we terminate Ms. Crothall's employment without cause or as a result of her disability, or she terminates her employment with good reason and Ms. Crothall executes a release of claims that she may have against us, we will continue to pay to Ms. Crothall her then-current base salary and benefits for the 18-month period following her date of termination (less any amounts paid to Ms. Crothall under our long-term disability program), a pro-rated bonus for the fiscal year of her termination of employment, and certain other benefits required by the terms of any of our applicable benefit plans. If Ms. Crothall's employment terminates as a result of her death, we will pay to her estate

or named beneficiaries an amount equal to one month of her then-current base salary, the proceeds of any life insurance policy maintained by us covering her life, and certain other benefits required by the terms of any of our applicable benefit plans as if she had been terminated by us without cause. If Ms. Crothall's employment is terminated or not renewed at the end of the current term of the agreement and Ms. Crothall executes a release of claims that she may have against us, we will continue to pay to Ms. Crothall her then-current base salary and benefits for the 12-month period following her date of termination, a pro-rated bonus for the fiscal year of her termination of employment, and certain other benefits required by the terms of any of our applicable benefit plans. If it would be economically advantageous to her for certain tax purposes, certain severance payments to Ms. Crothall may be reduced following a change of control.

In addition, in the event that we terminate Ms. Crothall's employment without cause, Ms. Crothall terminates her employment for good reason, or her employment terminates six months before or 12 months after the date of a change of control, all of her then-unvested stock options, restricted stock, or other stock awards will immediately and fully vest. Further, on the date of a change of control, Ms. Crothall will receive accelerated vesting on 24 months of her then-unvested stock options, restricted stock, or other stock awards.

Ms. Crothall's employment agreement also contains non-competition provisions prohibiting her from competing against us during the term of her employment agreement and for two years thereafter without our prior written consent.

**Richard Baron.** An employment agreement with Mr. Baron, who serves as our Vice President Finance and Chief Financial Officer, will be effective upon the closing of this offering. The agreement expires on December 31, 2006. Mr. Baron receives an annual base salary of \$220,200, subject to increases upon an annual review by our board of directors. Mr. Baron is permitted to participate in any short-term or long-term incentive compensation programs that we may establish for our senior level officers generally. Any payment under a short-term or long-term program will be based on Mr. Baron's performance and our business results as determined by our board of directors.

Either Mr. Baron or we may terminate his employment at any time, subject to certain severance payments and other benefits depending on the reason for such termination. If we terminate Mr. Baron's employment for cause or he voluntarily terminates his employment for any reason, Mr. Baron will receive only those benefits required to be provided to Mr. Baron by the terms of any of our applicable benefit plans. If we terminate Mr. Baron's employment without cause and he executes a release of claims that he may have against us, we will continue to pay to Mr. Baron his then-current base salary and benefits for the 12-month period following his date of termination and certain other benefits required by the terms of any of our applicable benefit plans.

In addition, in the event that we terminate Mr. Baron's employment without cause, 12 months of his then-unvested stock options, restricted stock, or other awards will immediately and fully vest.

Mr. Baron's employment agreement also contains non-competition provisions prohibiting Mr. Baron from competing against us during the term of the employment agreement and for two years thereafter without our prior written consent.

#### **Change of Control Agreements**

Agreements with each of our executive officers (other than Ms. Crothall) that contain provisions that will be triggered in the event of a change of control will be effective as of the closing of this offering. Upon a change of control, such executive officers will receive accelerated vesting on 24 months of their then-unvested stock options. In the event that such an executive officer's employment with us is terminated for certain reasons during the period commencing 30 days before or one year after the date of a change of control, such executive officer will receive a lump sum payment equal to one year of his or her then-current base salary. In addition, in the event that such an executive officer has remained employed by

us from the consummation of a change of control through the one-year anniversary of such change of control, such executive officer will receive a lump sum payment equal to one year of his or her then-current base salary.

These agreements terminate if a change of control does not occur on or before December 31, 2006.

## **RELATED PARTY TRANSACTIONS**

### **Legal Services**

One of our directors, A. Peter Parsons, is a partner in the law firm of Davis Wright Tremaine LLP. This firm represented us in a lawsuit initiated against a former employee in 2003. In such lawsuit, we asserted claims for conversion and breach of contract. The lawsuit has been settled. We paid this firm \$23,350 in 2003 in connection with this dispute.

### **Insurance Coverage**

One of our directors, William A. Graham, IV, is the majority owner of The Graham Company, which has been our insurance broker since 1996. We purchase all of our insurance policies, other than health insurance, from The Graham Company. The Graham Company received commissions of \$139,918, \$83,827, \$232,210, and \$84,340 in 2001, 2002, 2003, and the three months ended March 31, 2004, respectively, from the sale of insurance to us. We believe that the price we have paid for our insurance coverage has been either market or below market price. We also believe that the commissions received by The Graham Company from the sale of insurance to us were customary for the insurance industry.

### **Guaranty of Indebtedness**

We have a \$250,000 line of credit facility with a bank that bears interest at 1.5% above the bank's prime rate. The line of credit expires on January 5, 2005. There was \$250,000 outstanding under the line of credit on March 31, 2004. Our President and Chief Executive Officer, Katherine D. Crothall, has guaranteed all obligations under this credit facility.

### **Loan from Director**

On February 14, 2001, we satisfied a \$1,000,000 loan from one of our directors, William A. Graham, IV, in consideration of our issuance to him of 100,000 shares of our Series B Preferred Stock.

### **Preferred Stock and Unit Issuances**

From January 2001 through November 2003, we sold shares of our preferred stock in private financings as follows:

a total of 1,500,000 shares of our Series B Preferred Stock at a price of \$10.00 per share in January 2001 and February 2001;

a total of 2,395,900 shares of our Series C Preferred Stock at a price of \$12.50 per share in October 2001, January 2002, and May 2002; and

a total of 1,348,624 units at a price of \$12.50 per unit in January, March, April and November 2003. Each unit consisted of one share of our Series C Preferred Stock and one warrant to purchase 0.9 shares of our Series C Preferred Stock exercisable at \$12.50 per whole share.

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Immediately prior to the closing of this offering, warrants to purchase shares of our Series C Preferred Stock will be exercised pursuant to the cashless exercise provision of these warrants. Then, each share of our preferred stock will be converted automatically into 1.333 shares of our common stock. The purchasers of these shares of preferred stock are entitled to certain registration rights. See Description of Capital Stock Registration Rights. The investors in these financings included the following executive officers, directors, and holders of more than 5% of our securities and their affiliated entities:

Investor	Series B	Series C	Series C Warrants
Katherine D. Crothall <sup>(1)</sup>		725,000	155,700
Edward Cahill <sup>(2)</sup>	500,000	157,577	50,234
Graeme Crothall <sup>(3)</sup>		725,000	155,700
William A. Graham, IV <sup>(4)</sup>	150,000	640,000	216,000
Thomas Morse <sup>(5)</sup>	300,000	116,929	32,156
Johnson & Johnson Development Corporation	400,000	657,844	412,060

(1) Includes shares and warrants held by Ms. Crothall's husband, Graeme Crothall, and various trusts for the benefit of their children and her husband's siblings.

(2) Includes shares and warrants held by HLM/ CB Fund II, L.P., HLM Opportunities Fund, L.P., and HLM U/ H Fund, L.P. Mr. Cahill is an affiliate of these funds.

(3) Includes shares and warrants held by Mr. Crothall's wife, Katherine D. Crothall, and various trusts for the benefit of their children and his siblings.

(4) Includes shares held by various trusts for the benefit of Mr. Graham's children.

(5) Includes shares and warrants held by Liberty Advisors, Liberty Ventures I, L.P., and Liberty Ventures II, L.P. Mr. Morse is the sole stockholder of Liberty Advisors, the president and sole stockholder of the general partner of Liberty Ventures I, L.P., and a managing director of the general partner of Liberty Ventures II, L.P.

### PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of April 30, 2004 (assuming the Pre-offering Transactions had occurred) by:

each person, or group of affiliated persons, known by us to own beneficially more than 5% of our outstanding common stock;

each of our directors;

each of our named executive officers; and

all of our current executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. Shares of our common stock subject to options or warrants currently exercisable or exercisable within 60 days of April 30, 2004, are deemed outstanding for calculating the percentage of outstanding shares of the person holding these options or warrants, but are not deemed outstanding for calculating the percentage of any other person. Percentage of beneficial ownership is based upon 14,281,753 shares of our common stock outstanding as of April 30, 2004 (as adjusted for the Pre-offering transactions) and 18,531,753 shares of our common stock outstanding after this offering. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name.

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Except as otherwise indicated, the address of each of the persons in this table is as follows: c/o Animas Corporation, 200 Lawrence Drive, West Chester, Pennsylvania 19380.

Beneficial Owner	Beneficial Ownership	Options and Warrants Exercisable Within 60 Days	Percentage of Shares Outstanding	
			Before Offering	After Offering
<b>Named Executive Officers and Directors</b>				
Katherine D. Crothall <sup>(1)</sup>	2,369,850	69,334	17.0%	13.1%
Richard Baron <sup>(2)</sup>	21,334	48,934	*	*
Audrey Finkelstein		98,000	*	*
John Holly		28,401	*	*
Patrick Paul		17,334	*	*
Edward Cahill <sup>(3)</sup>	901,885	14,668	6.4%	4.9%
Graeme Crothall <sup>(4)</sup>	922,034	14,668	6.6%	5.1%
William A. Graham, IV <sup>(5)</sup>	1,735,809	48,002	12.4%	9.6%
David Joseph		48,002	*	*
John J. McDonough		14,668	*	*
Thomas Morse <sup>(6)</sup>	571,983	14,668	4.1%	3.2%
A. Peter Parsons <sup>(7)</sup>	369,711	22,334	2.7%	2.1%
<b>All Other 5% Stockholders</b>				
Johnson & Johnson Development Corporation <sup>(8)</sup>	1,616,488		11.3%	8.7%
All directors and executive officers as a group (14 persons)	6,541,184	461,147	47.5%	36.9%

\*Represents less than 1% of the outstanding shares of our common stock.

(1) Includes 988,933 shares of our common stock held in various trusts in which Ms. Crothall is a trustee. Ms. Crothall disclaims beneficial ownership of the shares held in the various trusts in which she is a trustee.

(2) Mr. Baron jointly holds these shares with his wife.

(3) Represents 225,471 shares of our common stock held by HLM/ CB Fund II, L.P., 135,281 shares of our common stock held by HLM Opportunities Fund, L.P., and 541,132 shares of our common stock held by HLM U/ H Fund, L.P. Mr. Cahill is an affiliate of HLM/ CB Fund II, L.P., HLM Opportunities Fund, L.P., and HLM U/ H Fund, L.P. Mr. Cahill disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest in the named funds. Mr. Cahill's address is c/o HLM Venture Partners is 222 Berkeley Street, 21st Floor Boston, MA 02116.

(4) Includes 346,001 shares of our common stock held by various trusts in which Mr. Crothall is a trustee. Mr. Crothall disclaims beneficial ownership of the shares held in the various trusts in which he is a trustee, except to the extent that he is the beneficiary of any of such trusts.

(5) Includes 298,222 shares of our common stock held by various trusts in which Mr. Graham is the trustee. Mr. Graham disclaims beneficial ownership of the shares held in various trusts in which he is the trustee. Mr. Graham's address is c/o The Graham Company, The Graham Building, One Penn Square West, Philadelphia, PA 19102.

(6) Represents 1,837 shares held by Liberty Advisors, 285,073 shares held by Liberty Ventures I, L.P., and 285,073 shares held by Liberty Ventures II, L.P. Mr. Morse is the sole stockholder of Liberty Advisors. Mr. Morse is also the president and sole stockholder of Liberty Ventures, Inc., which is the general partner of Liberty Ventures I, L.P. Mr. Morse is also a managing director of the general partner of Liberty Ventures II, L.P. Mr. Morse disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest in the named funds. Mr. Morse's address is c/o Liberty Venture Partners is One Commerce Square, 2005 Market St., Suite 2040 Philadelphia, PA 19103-7012.

(7) Includes 351,422 shares of our common stock held by a trust in which Mr. Parsons is a trustee. Mr. Parsons disclaims beneficial ownership of the shares held in the trust in which he is the trustee.

(8) The address of Johnson & Johnson Development Corporation is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

**DESCRIPTION OF CAPITAL STOCK**

Upon the closing of this offering, our authorized capital stock, after giving effect to the conversion of all of our outstanding preferred stock into our common stock and the amendment and restatement of our certificate of incorporation, will consist of 100,000,000 shares of our common stock, \$0.01 par value, and 10,000,000 shares of our preferred stock, \$0.01 par value. The following description summarizes the terms



of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our form of amended and restated certificate of incorporation and our form of amended and restated bylaws, as in effect immediately following the closing of this offering, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

### **Common Stock**

As of April 30, 2004, there were 4,082,495 shares of our common stock outstanding and held by 115 stockholders of record. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Our stockholders do not have cumulative voting rights in the election of directors. Subject to preferences that may be granted to any then-outstanding preferred stock, holders of our common stock are entitled to receive ratably only those dividends as may be declared by our board of directors out of funds legally available therefor, as well as any distributions to our stockholders. See **Dividend Policy**. In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all of our assets remaining after we pay our liabilities and distribute the liquidation preference of any then-outstanding preferred stock. Holders of our common stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to our common stock.

### **Common Stock Warrants**

As of April 30, 2004, there were warrants outstanding to purchase 269,501 shares of our common stock at a weighted average exercise price of \$5.64 per share. Of these warrants, warrants to purchase 116,478 shares of our common stock at a weighted average exercise price of \$4.72 per share will terminate at the closing of this offering unless earlier exercised.

### **Preferred Stock**

As of April 30, 2004, there were 7,109,488 shares of our preferred stock outstanding. Upon the closing of this offering, each outstanding share of our preferred stock will convert into 1.333 shares of our common stock. Following the conversion of our preferred stock, our certificate of incorporation will be amended and restated to delete all references to the prior series of preferred stock, and 10,000,000 shares of undesignated preferred stock will be authorized.

Our board of directors will have the authority, without further action by our stockholders, to issue our preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences, and privileges include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of our holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of our preferred stock could have the effect of delaying, deferring, or preventing a change in our control. We have no present plan to issue any shares of our preferred stock.

### **Preferred Stock Warrants**

As of April 30, 2004, there were warrants outstanding to purchase 1,211,998 shares of our Series C Preferred Stock at an exercise price of \$12.50 per share. Of these warrants, warrants to purchase 5,000 shares of our Series C Preferred Stock will be converted at the closing of this offering into warrants to purchase 6,666 shares of our common stock. All of the remaining warrants to purchase our Series C Preferred Stock will be cashless exercised immediately prior to the closing of this offering for an aggregate of 452,624 shares of our Series C Preferred Stock. Immediately following the cashless exercise of these warrants, such shares of Series C Preferred Stock will be converted into our common stock. See **Preferred Stock**.



## Registration Rights

Upon closing of this offering, the holders of 10,082,780 shares of our common stock and 69,360 shares subject to warrants to purchase our common stock are entitled to certain rights with respect to the registration of their shares under the Securities Act.

Under a registration rights agreement and an investor rights agreement by and among us and certain of our stockholders, holders may demand that we file a registration statement under the Securities Act covering some or all of the holders' registrable securities. The registration rights agreement and investor rights agreement limit the number of demand registrations that we are required to make on behalf of the holders, and also require a minimum gross proceeds of \$15 million. In an underwritten offering, the managing underwriter has the right, subject to specified conditions, to limit the number of registrable securities if it is believed such registrations will exceed the number that can be sold at the desired price. In such a case, 20% of such securities able to be registered will be allocated to those holders having registration rights pursuant to the investor rights agreement and the remaining 80% will be allocated to those holders having registration rights pursuant to the registration rights agreement. The holders also have unlimited rights to require us to register their shares on Form S-3 once we are eligible to use such form. In general, we will bear all fees, costs, and expenses of registrations, other than underwriting discounts and commissions.

In addition, holders have certain "piggyback" registration rights. If we propose to register any of our equity securities under the Securities Act other than pursuant to demand registration rights noted above or specified excluded registrations, holders may require us to include all or a portion of their registrable securities in the registration and in any related underwriting. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of registrable securities. Additionally, such piggyback registrations are subject to delay or termination of the registration under certain circumstances. The underwriters named in this prospectus have notified us that no holders of registration rights will be permitted to include any of their shares in this offering.

## Anti-takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws

Upon closing of this offering, our amended and restated certificate of incorporation and bylaws will provide for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

The combination of the classification of our board of directors and lack of cumulative voting will make it more difficult for our stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for our stockholders or another party to effect a change in our management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in our control.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or in our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and in the policies furnished by them and to discourage certain types of transactions that may involve an actual or threatened change in our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in our management.

## Section 203 of the General Corporation Law of the State of Delaware

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a

period of three years following the date that such stockholder became an interested stockholder, with the following exceptions:

prior to such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines business combination to include the following:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges, or other financial benefits by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

#### **Nasdaq National Market Listing**

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

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is StockTrans, Inc. Its address is 44 W. Lancaster Avenue, Ardmore, PA 19003, and its telephone number is (610) 649-7300.

### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market could reduce prevailing market prices. Some shares will not be available for sale shortly after this offering because of contractual and legal restrictions on resale as described below. Sales of substantial amounts of our common stock in the public market after any of these restrictions on sale lapse could adversely affect the prevailing market price of our common stock and impair our ability to raise equity capital in the future.

Upon closing of this offering, we will have 18,531,753 shares of our common stock outstanding. Of these shares, the 4,250,000 shares sold in this offering will be freely transferable without restriction under the Securities Act, except for shares purchased by our affiliates, as that term is used under the Securities Act, which may generally be sold only in accordance with Rule 144 of the Securities Act.

The remaining 14,281,753 shares were sold by us in reliance on exemptions from the registration requirements of the Securities Act and are restricted securities within the meaning of Rule 144. Of these shares, approximately 14,000,000 shares will become eligible for sale, subject to the provisions of Rule 144, upon the expiration of lock-up agreements entered into between our underwriters and holders of substantially all of our shares of common stock, including all of our directors, executive officers and holders of more than 10% of our common stock. These lock-up agreements are effective for a period of 180 days after the date of this prospectus and prohibit, in general, the offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right, or warrant to purchase, lending, or otherwise transfer or disposal of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, or the entering into any swap or other arrangement that transfer to another, in whole or in part, any of the economic consequences of ownership of our common stock, without the prior written consent of the lead underwriters in this offering, Piper Jaffray & Co. and J.P. Morgan Securities Inc.

#### Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of this offering, a person who has beneficially owned restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

one percent of the number of shares of our common stock then outstanding, which will equal 185,318 shares immediately after the offering; and

the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 are also subject to requirements regarding the manner of sale, notice, and the availability of current public information about us. Rule 144 also provides that affiliates that sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

#### Rule 144(k)

Under Rule 144(k), a person who is not deemed to have been our affiliate at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, may sell those shares without complying with the manner-of-sale, public information, volume limitation or notice provisions of Rule 144.

#### Rule 701

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our 1998 Equity Compensation Plan and our 1996 Incentive Stock Plan may be resold, to the extent not subject to the lock-up agreements:

by persons other than affiliates, beginning 90 days after the effective date of this offering, subject only to the manner-of-sale provisions of Rule 144; and

by affiliates, subject to the manner-of-sale, current public information, and filing requirements of Rule 144, in each case, without compliance with the one-year holding period requirement of Rule 144.

As of April 30, 2004, options to purchase a total of 2,580,434 shares of our common stock were outstanding.

**Form S-8 Registration Statements**

We intend to file one or more registration statements on Form S-8 under the Securities Act following this offering to register the shares of our common stock that are issuable pursuant to our 2004 Employee Stock Purchase Plan, 2004 Equity Incentive Plan, 1998 Equity Compensation Plan, and 1996 Incentive Stock Plan. These registration statements are expected to become effective upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to the lock-up agreements and, if applicable, to Rule 144 limitations applicable to affiliates.

**UNDERWRITING**

The underwriters named below, for whom Piper Jaffray & Co., J.P. Morgan Securities Inc., and Thomas Weisel Partners LLC are acting as representatives, have agreed to purchase, subject to the terms of an underwriting agreement, the number of shares listed opposite their names below. The underwriters are committed to purchase and pay for all of the shares if any are purchased, other than those shares covered by the over-allotment option described below.

Underwriters	Number of Shares
Piper Jaffray & Co.	1,640,000
J.P. Morgan Securities Inc.	1,640,000
Thomas Weisel Partners LLC	820,000
Janney Montgomery Scott LLC	50,000
Legg Mason Wood Walker, Incorporated	50,000
RBC Capital Markets Corporation	50,000
Total	4,250,000

The underwriting agreement provides that the obligations of the several underwriters to purchase shares of our common stock are subject to the satisfaction of the conditions contained in the underwriting agreement, which include that:

the registration statement of which this prospectus is a part has been declared effective;

the representations and warranties made by us to the underwriters are true;

there is no material adverse change in our business;

the shares of our common stock to be sold in this offering have been approved for listing on The NASDAQ National Market; and

we deliver customary closing documents to the underwriters.

The underwriters have advised us that they propose to offer the shares initially to the public at \$15.00 per share. The underwriters propose to offer the shares to certain dealers at the same price less a concession of not more than \$0.63 per share. The underwriters may allow and the dealers may reallocate a concession of not more than \$0.10 per share on sales to certain other brokers and dealers. After this offering, these figures may be changed by the underwriters.

We have granted to the underwriters an over-allotment option to purchase up to an additional 637,500 shares of our common stock from us at the same price as to the public, and with the same underwriting discount, as set forth on the front cover of this prospectus. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any. To the extent the underwriters exercise the option, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares as it was obligated to purchase under the underwriting agreement.

The following table shows the underwriting discounts and commissions to be paid to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	Per Share	Aggregate Without Option	Aggregate With Option
Underwriting discounts and commission payable by us	\$1.05	\$4,462,500	\$5,131,875

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We estimate that the total expenses of this offering payable by us, excluding underwriting discounts and commissions, will be approximately \$2.3 million. We have agreed to indemnify the underwriters against certain liabilities that may be based upon an untrue statement of material fact contained in this prospectus,

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including civil liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have informed us that neither they, nor any other underwriter participating in the distribution of this offering, will make sales of our common stock offered by this prospectus to accounts over which they exercise discretionary authority without the prior specific written approval of the customer.

At our request, the underwriters have reserved up to 12,500 shares of the common stock being offered by this prospectus for sale to our directors, employees, business associates, and related persons at the initial public offering price. The sales will be made by Piper Jaffray & Co. through a directed share program. The purchasers of these shares will not be subject to a lock-up except as required by the Conduct Rules of the National Association of Securities Dealers, Inc. (NASD), which requires a 90-day lock-up if such purchaser is affiliated with or associated with an NASD member or if such purchaser or members of such purchaser's immediate family hold senior positions at financial institutions, or to the extent the purchasers are subject to a lock-up agreement with the underwriters as described below. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. These persons must commit to purchase no later than the close of business on the day following the date of this prospectus.

The offering of our shares of common stock is made for delivery when and if accepted by the underwriters and subject to prior sale and to withdrawal, cancellation, or modification of this offering without notice. The underwriters reserve the right to reject an order for the purchase of shares in whole or part.

Subject to certain exceptions, we and each of our directors, executive officers, and holders of substantially all of our shares of common stock have agreed not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether any transaction is to be settled by delivery of common stock or other securities, in cash or otherwise, without the prior written consent of Piper Jaffray & Co. and J.P. Morgan Securities Inc. for a period of 180 days after the date of this prospectus.

Prior to this offering, there has been no established trading market for our common stock. The initial public offering price for the shares of our common stock offered by this prospectus was negotiated between us and the underwriters immediately prior to this offering. Factors considered in determining the initial public offering price included:

the history of, and the prospects for, the industry in which we compete;

our past and present operations;

our historical results of operations;

our prospects for future earnings;

the recent market prices of securities of generally comparable companies; and

the general condition of the securities markets at the time of this offering and other relevant factors.

The initial public offering price of our common stock may not correspond to the price at which our common stock will trade in the public market subsequent to this offering, and an active public market for our common stock may never develop or, if it does develop, continue after this offering.

To facilitate this offering, the underwriters may engage in transactions that stabilize, maintain, or otherwise affect the price of our common stock during and after this offering. Specifically, the underwriters may over-allot or otherwise create a short position in our common stock for their own account by selling more shares of our common stock than have been sold to them by us. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In





determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

In addition, the underwriters may stabilize or maintain the price of our common stock by bidding for or purchasing shares of our common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in this offering are reclaimed if shares of our common stock previously distributed in this offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of our common stock to the extent that it discourages resales of our common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on The NASDAQ National Market or otherwise and, if commenced, may be discontinued at any time.

As of the date of this prospectus, U.S. Bancorp Piper Jaffray ECM Fund II, LLC ( ECM Fund ) and ECM Fund II, Investors 03 ( Investors Fund ) own 120,000 and 40,000 shares, respectively, of our Series C Preferred Stock. Each of these funds consists of individual investors who are or were associated with Piper Jaffray & Co., one of the representatives in this offering. After giving effect to the Pre-offering Transactions, each of ECM Fund and Investors Fund will own 160,000 and 53,333 shares of our common stock, respectively. Each of ECM Fund and Investors Fund has agreed to be subject to the lock-up agreements described above.

#### **LEGAL MATTERS**

The validity of the shares of our common stock offered hereby is being passed upon for us by Pepper Hamilton LLP, Philadelphia, Pennsylvania. Certain legal matters in connection with this offering will be passed upon for the underwriters by Ballard Spahr Andrews & Ingersoll, LLP, Philadelphia, Pennsylvania.

#### **EXPERTS**

The consolidated financial statements of Animas Corporation and subsidiary as of December 31, 2002 and 2003 and for each of the years in the three-year period ended December 31, 2003 have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent accountants, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We filed with the SEC a registration statement on Form S-1 under the Securities Act for the shares of our common stock to be sold in this offering. This prospectus does not contain all of the information in the registration statement and the exhibits that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits that were filed with the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits that were filed with the registration statement may be inspected without charge at the public reference facilities maintained by the SEC in Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from the SEC upon payment of the prescribed fee. Information on the operation of the public reference facilities may be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the site is <http://www.sec.gov>. You may also request copies of these filings, at no cost, by telephone at (610) 644-8990 or by mail to: Animas Corporation, 200 Lawrence Drive, West Chester, Pennsylvania 19380, Attention: Investor Relations.

Upon closing of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act, and, in accordance with such requirements, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection and copying at the public reference facilities and website of the SEC referred to above. We intend to furnish our stockholders with annual reports containing financial statements audited by our independent accountants.

**ANIMAS CORPORATION AND SUBSIDIARY**

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**INDEPENDENT AUDITORS REPORT**

**The Board of Directors and Stockholders of**

**Animas Corporation:**

We have audited the accompanying consolidated balance sheets of Animas Corporation and subsidiary as of December 31, 2002 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Animas Corporation and subsidiary as of December 31, 2002 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Philadelphia, Pennsylvania

April 27, 2004 except  
as to Note 15 which is as of May 7, 2004

## ANIMAS CORPORATION AND SUBSIDIARY

## Consolidated Balance Sheets

	December 31,		March 31,
	2002	2003	2004
			(unaudited)
	(in thousands except share data)		
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 1,134	\$ 384	\$ 556
Accounts receivable, net of allowance for doubtful accounts of \$733 in 2002, \$1,285 in 2003 and \$1,404 in 2004	7,066	13,178	12,307
Inventories	2,724	3,335	4,961
Cost associated with deferred revenue		1,025	2,140
Prepaid expenses and other current assets	353	575	236
	<u>11,277</u>	<u>18,497</u>	<u>20,200</u>
Property and equipment, net	3,932	3,899	4,135
Deposits and other assets	109	297	176
Deferred public offering costs			1,542
Restricted cash		550	
	<u>15,318</u>	<u>23,243</u>	<u>26,053</u>
	<u>\$ 15,318</u>	<u>\$ 23,243</u>	<u>\$ 26,053</u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>			
Current liabilities:			
Lines of credit	\$ 250	\$ 2,657	\$ 3,967
Current portion of long-term debt	436	462	501
Accounts payable	2,642	2,752	6,605
Accrued expenses	2,637	3,283	4,205
Deferred revenue		5,179	9,658
	<u>5,965</u>	<u>14,333</u>	<u>24,936</u>
Total current liabilities	5,965	14,333	24,936
Other liabilities	1,039	1,140	1,021
Long-term debt	852	467	518
	<u>7,856</u>	<u>15,940</u>	<u>26,475</u>
Total liabilities	7,856	15,940	26,475
Commitments and contingencies (Note 8)			
Stockholders equity (deficit):			
Series A, B, and C preferred stock, \$0.01 par value; authorized 8,353,200 shares; issued and outstanding 5,749,100 in 2002, 7,097,724 in 2003 and 7,109,488 in 2004 (liquidation value \$86,549 as of December 31, 2003 and \$88,166 as of March 31, 2004)	58	71	71
Common stock, \$0.01 par value; authorized 24,000,000 shares in 2002 and 2003, 100,000,000 in 2004; issued and outstanding 3,865,982 shares in 2002, 3,987,282 in 2003 and 4,082,495 in 2004	39	40	41
Additional paid-in capital	64,910	90,544	90,951
Deferred compensation	(53)	(178)	(227)

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Accumulated deficit	(57,492)	(83,174)	(91,258)
	<u>7,462</u>	<u>7,303</u>	<u>(422)</u>
Total stockholders' equity (deficit)			
Total liabilities and stockholders' equity (deficit)	\$ 15,318	\$ 23,243	\$ 26,053

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

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## ANIMAS CORPORATION AND SUBSIDIARY

## Consolidated Statements of Operations

	Years Ended December 31,			Three Months Ended March 31,	
	2001	2002	2003	2003	2004
	(in thousands except share and per share data)				
	(unaudited)				
Net revenues	\$ 10,040	\$ 23,598	\$ 34,120	\$ 7,380	\$ 4,837
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 (Note 7)			(7,878)	(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 (Note 13)			\$ (1.99)		\$ (0.58)
Unaudited pro forma weighted average shares outstanding basic and diluted (Note 13)			12,889,179		13,979,299

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





## ANIMAS CORPORATION AND SUBSIDIARY

## Consolidated Statements of Stockholders Equity (Deficit)

Years Ended December 31, 2001, 2002, and 2003 and the Three Months Ended March 31, 2004

	Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount				
(in thousands except share and per share data)								
Balance, January 1, 2001	1,853,200	\$ 19	3,845,149	\$ 39	\$ 19,956	\$	\$(19,617)	\$ 397
Sale of preferred stock at \$10 per share, net of offering costs of \$409	1,500,000	15			14,576			14,591
Sale of preferred stock at \$12.50 per share, net of offering costs of \$62	1,814,355	18			22,599			22,617
Issuance of common stock for interest incurred			3,500		26			26
Issuance of stock options for services rendered					178			178
Exercise of stock options to purchase common stock			8,000		38			38
Net loss							(18,501)	(18,501)
Balance, December 31, 2001	5,167,555	52	3,856,649	39	57,373		(38,118)	19,346
Sale of preferred stock at \$12.50 per share, net of offering costs of \$34	581,545	6			7,229			7,235
Issuance of stock options for services rendered					184			184
Exercise of stock options to purchase common stock			9,333		44			44
Deferred compensation					80	(80)		
Amortization of deferred compensation						27		27
Net loss							(19,374)	(19,374)
Balance, December 31, 2002	5,749,100	58	3,865,982	39	64,910	(53)	(57,492)	7,462
Sale of preferred stock at \$12.50 per share, net of offering costs of \$158	1,348,624	13			16,686			16,699
Issuance of stock options for services rendered					591			591
Exercise of stock options to purchase common stock			121,300	1	314			315
Deferred compensation					165	(165)		
Amortization of deferred compensation						40		40
Net loss							(25,682)	(25,682)
Deemed dividend (Note 7)					7,878			7,878
Balance, December 31, 2003	7,097,724	71	3,987,282	40	90,544	(178)	(83,174)	7,303
Exercise of stock warrants to purchase preferred stock (unaudited)	11,764				147			147
Exercise of stock options and warrants to purchase common stock (unaudited)			89,880	1	184			185
Deferred compensation (unaudited)			5,333		76	(76)		
Amortization of deferred compensation (unaudited)						27		27

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Net loss (unaudited)							(8,084)	(8,084)
Balance, March 31, 2004 (unaudited)	7,109,488	\$ 71	4,082,495	\$ 41	\$90,951	\$ (227)	\$ (91,258)	\$ (422)

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

## ANIMAS CORPORATION AND SUBSIDIARY

## Consolidated Statements of Cash Flows

	Years Ended December 31,			Three Months Ended March 31,	
	2001	2002	2003	2003	2004
	(amounts in thousands)				
	(unaudited)				
Cash flows from operating activities:					
Net loss	\$ (18,501)	\$ (19,374)	\$ (17,804)	\$ (4,470)	\$ (8,084)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	656	1,180	1,679	360	554
Non-cash compensation and interest expense	178	211	631	37	28
Bad debt expense	445	316	889	585	119
Other	26	(20)			11
Changes in net assets and liabilities:					
Accounts receivable, net	(1,804)	(4,573)	(7,001)	(830)	752
Inventories	(357)	(1,537)	(611)	201	(1,626)
Prepaid expenses and other current assets	259	(46)	(222)	(270)	339
Deposits and other assets	(1)	(26)	(188)	(16)	121
Restricted cash			(550)		550
Cost associated with deferred revenue			(1,025)		(1,115)
Accounts payable	260	1,456	110	286	2,660
Accrued expenses and other liabilities	1,600	752	747	216	523
Deferred revenue	(490)		5,179		4,479
Net cash used in operating activities	(17,729)	(21,661)	(18,166)	(3,901)	(689)
Cash flows from investing activities:					
Purchases of property and equipment	(2,084)	(1,984)	(1,524)	(410)	(582)
Net cash used in investing activities	(2,084)	(1,984)	(1,524)	(410)	(582)
Cash flows from financing activities:					
Proceeds from lines of credit	460	573	3,885	1,000	6,104
Repayments on lines of credit	(460)	(323)	(1,478)	(500)	(4,794)
Proceeds from issuance of common stock	38	44	315	10	184
Proceeds from long-term debt		1,000			
Repayments on long-term debt	(258)	(357)	(481)	(106)	(129)
Proceeds from sale of preferred stock	36,208	7,235	16,699	11,417	147
Payments of public offering costs					(69)
Net cash provided by financing activities	35,988	8,172	18,940	11,821	1,443
Net increase (decrease) in cash	16,175	(15,473)	(750)	7,510	172
Cash and cash equivalents at beginning of year	432	16,607	1,134	1,134	384
Cash and cash equivalents at end of year	\$ 16,607	\$ 1,134	\$ 384	\$ 8,644	\$ 556

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

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**ANIMAS CORPORATION AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)**

**(1) Organization and Description of Business**

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

The Company has incurred operating losses since inception, has an accumulated deficit of \$83,174 as of December 31, 2003 and has been dependent upon external financing to fund operations. The Company expects to incur additional operating losses for most of 2004. The Company believes its cash and cash equivalents as of December 31, 2003, proceeds available under its lines of credit (see Note 6), and cash generated from operations will be sufficient to fund the Company's operations into 2005.

The Company may require additional financing in the future. There can be no assurance that the Company will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to the Company's stockholders. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company's business, operating results and financial condition.

**(2) Summary of Significant Accounting Policies**

**Unaudited Interim Results.** The financial statements as of March 31, 2004 and for the three months ended March 31, 2003 and 2004 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position and the results of operations and cash flows for the three months ended March 31, 2003 and 2004 have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or eliminated. The results for the three months ended March 31, 2004 are not necessarily indicative of the results to be expected for the year ending December 31, 2004 or for any other interim period.

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

**Cash and Cash Equivalents and Restricted Cash.** The Company considers all highly liquid debt instruments with an original maturity of three months or less when purchased to be a cash equivalent. Restricted cash is used as collateral for a letter of credit (see Note 8).

**Accounts Receivable Allowance for Doubtful Accounts.** Accounts receivable consist of amounts due from third party payors (non-governmental and governmental), distributors, and patients. In estimating the

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

collectability of our accounts receivable, the Company analyzes historical bad debts, payor and patient concentrations, payor and patient credit-worthiness, and current economic trends. These allowances are recorded in the period when the revenue is recorded. Allowances are adjusted currently for any changes in estimated collections.

Accounts receivable are net of allowances for doubtful accounts of \$733 and \$1,285 at December 31, 2002 and 2003, respectively. Bad debt expense was \$445, \$316 and \$889 for the fiscal years 2001, 2002, and 2003, respectively. The related write-offs of accounts receivable were \$77, \$33, and \$337 for these years, respectively.

**Inventories.** Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Cost for pumps includes material, labor and manufacturing overhead. Ancillary supplies inventory, and materials and parts for pumps include material costs only. Obsolete inventory is written off monthly.

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

Laboratory equipment	5 years
Computer equipment	3 years
Manufacturing equipment	5 years
Leasehold improvements	3 years
Office furniture and equipment	3 to 7 years

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

**Product Warranties.** The Company provides a four-year warranty on its insulin pumps. For proper matching of warranty costs with related revenues an estimated warranty expense is determined based on historical experience, expected future claims and the estimated cost to settle the claims. Such costs are recorded at the time of shipment. At December 31, 2002, and 2003, accrued product warranties totaled \$1,775 and \$1,734, respectively, and are classified as a current liability in accrued expenses (\$756 and \$608 see Note 5) and are classified as a long-term liability in other liabilities (\$1,019 and \$1,126, respectively) in the accompanying consolidated balance sheets. At March 31, 2004, accrued product warranties totaled \$1,743 (of which \$733 is in accrued expenses and \$1,010 is classified as a long-term

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

liability in other liabilities in the accompanying balance sheet. A tabular reconciliation of the changes in the Company's product warranty liability is as follows:

	Year Ended December 31,		Three Months Ended March 31,
	2002	2003	2004
Balance at beginning of period	\$ 1,604	\$ 1,775	\$ 1,734
Warranty expense	1,160	820	596
Warranty claims settled	(989)	(861)	(587)
Balance at end of period	\$ 1,775	\$ 1,734	\$ 1,743

Given the four-year warranty period of the Company's insulin pumps, the portion of the warranty accrual classified as long-term represents the Company's estimate of costs to settle warranty claims to be incurred in excess of one year from the balance sheet date.

**Other Comprehensive Loss.** Comprehensive loss represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. No separate statement of comprehensive loss has been presented because comprehensive loss was equal to net loss in each of the years ended December 31, 2001, 2002, and 2003.

**Revenue Recognition.** Revenues are generated primarily from the sale of insulin pumps and ancillary supplies. Customers do not have any right of return or any right to cancel or terminate the sale once the pumps or ancillary supplies are shipped. Pump and ancillary supplies net revenues are recognized upon shipment in accordance with Staff Accounting Bulletin No. 104 (SAB 104). In accordance with EITF 00-21 Accounting for Revenue Arrangements with Multiple Deliverables, (EITF 00-21) in instances where the Company provides pump operation training, the Company defers the fair value of the training until it has been delivered. The Company bases the fair value of the training on the historical amount the Company has paid to independent service providers for training patients on the operation of the pump. Though the insulin pump has standalone value, there is no objective evidence as to the pump's fair value since the Company is reimbursed the same amount with or without training. As a result, the residual method under EITF 00-21 is utilized. As of December 31, 2003 and March 31, 2004, the Company had no deferred revenue under EITF 00-21 since the Company deferred the recognition of revenue for all pumps sold domestically between November 1, 2003 and December 31, 2003 and January 1, 2004 and March 31, 2004. See discussion of the IR 1200 upgrade program below.

In 2003, approximately 80% to 85% of the Company's products were sold directly to patients. The Company bills directly the healthcare payors on behalf of the patient. Levels of payments from third party payors vary depending upon the specific benefits provided under each patient's coverage. At the time of sale, the Company records revenue net of a contractual allowance which represents the difference between the established selling price and third party payor payments.

As noted above, in October 2003, the Company received FDA clearance for its IR 1200 pump. The Company began shipping the IR 1200 in April 2004. In November 2003, the Company initiated an upgrade program in which the Company offered to each new patient purchasing an IR 1000 pump, during

ANIMAS CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
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the upgrade period, to upgrade to the IR 1200 when it becomes available. All IR 1000 pumps shipped to new patients domestically between November 1, 2003 and March 31, 2004 are subject to the upgrade program. As required by SAB 104, the Company deferred the recognition of net revenues on all pump shipments with an upgrade obligation. As of March 31, 2004, the Company had deferred revenues of \$9,658 and related costs associated with deferred revenue of \$2,140. Net revenue will be recognized when the Company ships 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 the pumps are returned to the Company. When the Company ships an IR 1200 as a replacement pump, the Company will record the cost of the IR 1200 pump as cost of products sold at that time. It is anticipated that the upgrade of pumps under this program will be completed by July 31, 2004. As a result of this program, the Company's net revenues for the second and third quarters of 2004 will be increased by the recognition of revenues deferred from previous quarters, as the Company ships upgraded pumps or patients decline the upgrade. A delay or acceleration of the Company's 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.

Revenues from products sold directly to domestic and international distributors are recognized upon shipment, and are approximately 15% to 20% of annual Company net revenues. Distributors have no right of return. The Company has no post-shipment obligations to its distributors.

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

**Advertising Costs.** Advertising costs, included in selling, general and administrative expenses, are expensed as incurred. Advertising expenses in 2001, 2002, and 2003 were \$90, \$111, and \$98, respectively.

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

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

Had the Company determined compensation cost for options granted during the years ended December 31, 2001, 2002, and 2003, and the three months ended March 31, 2003 and 2004 based on the fair value



## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

method, at the grant date under SFAS No. 148, the Company's net loss and net loss per share would have been increased to the pro forma amounts indicated below:

	Years Ended December 31,			Three Months Ended March 31,	
	2001	2002	2003	2003	2004
Net loss attributable to common stockholders, as reported	\$ (18,501)	\$ (19,374)	\$ (25,682)	\$ (9,381)	\$ (8,084)
Add Non-cash employee compensation as reported		159	501	26	8
Deduct Total stock-based employee compensation expense determined under fair value-based method for pro forma net loss	(245)	(743)	(385)	(97)	(121)
Pro forma net loss attributable to common stockholders	\$ (18,746)	\$ (19,958)	\$ (25,566)	\$ (9,452)	\$ (8,197)
Loss attributable to common stockholders per share:					
Basic and diluted, as reported	\$ (4.80)	\$ (5.02)	\$ (6.64)	\$ (2.43)	\$ (2.07)
Basic and diluted, pro forma	\$ (4.86)	\$ (5.17)	\$ (6.61)	\$ (2.44)	\$ (2.10)

See discussion of fair value assumptions in Note 7.

**Net Loss per Common Share.** Net loss per common share is computed in accordance with SFAS No. 128, Earnings per Share. Under the provisions of SFAS No. 128, basic net loss per share (Basic EPS) is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted-average number of common shares and common equivalent shares then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, shares issuable upon the exercise of stock options and warrants and the conversion of preferred stock upon the exercise of warrants. For the three years ended December 31, 2003, Diluted EPS is identical to Basic EPS as the Company is in a net loss position and the common equivalent shares are considered anti-dilutive. As of December 31, 2003, common equivalents consisted of 2,614,608 common stock options, 1,223,762 Series C warrants, and 310,727 common warrants (see Note 7). See Note 13 regarding Unaudited Pro Forma Net Loss per Common Share.

**Use of Estimates.** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Some of the more significant estimates include the allowance for doubtful accounts, contractual allowances, and the warranty accrual. Actual amounts could differ from those estimates.

**New Accounting Pronouncement.** In May 2003, the FASB issued SFAS 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



## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
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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 the Company's financial position or results of operations.

**(3) Inventories**

Inventories consist of the following as of:

	December 31,		March 31, 2004
	2002	2003	
Raw material	\$ 1,023	\$ 1,064	\$ 1,477
Work in process	650	423	1,618
Finished goods	1,051	1,848	1,866
	<u>\$ 2,724</u>	<u>\$ 3,335</u>	<u>\$ 4,961</u>

**(4) Property and Equipment**

Property and equipment consist of the following as of:

	December 31,		March 31, 2004
	2002	2003	
Laboratory equipment	\$ 260	\$ 281	\$ 315
Computer equipment	1,834	2,272	2,351
Manufacturing equipment	1,761	2,750	3,060
Leasehold improvements	642	727	727
Furniture and equipment	970	1,071	1,284
Construction in progress	763	775	922
	<u>6,230</u>	<u>7,876</u>	<u>8,659</u>
Less accumulated depreciation and amortization	<u>(2,298)</u>	<u>(3,977)</u>	<u>(4,524)</u>
	<u>\$ 3,932</u>	<u>\$ 3,899</u>	<u>\$ 4,135</u>

Depreciation and amortization expense was \$656, \$1,180 and \$1,679 for the years ended December 31, 2001, 2002 and 2003, respectively. Depreciation and amortization expense was \$360 and \$554 for the three months ended March 31, 2003 and 2004, respectively.

**(5) Accrued Expenses**

Accrued expenses consist of the following at:

	December 31,	March 31,
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	<u>2002</u>	<u>2003</u>	<u>2004</u>
Salaries and related expenses	\$ 1,406	\$ 1,963	\$ 2,784
Other accrued expenses	475	712	688
Current portion of warranty accrual (Note 2)	756	608	733
	<u>          </u>	<u>          </u>	<u>          </u>
	\$2,637	\$3,283	\$4,205
	<u>          </u>	<u>          </u>	<u>          </u>

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## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

**(6) Lines of Credit and Long-term Debt**

The Company has a \$250 line of credit facility with a bank that bears interest at 1.5% above the bank's prime rate (5.5% at December 31, 2003). The line of credit expires on January 5, 2005. The Company had an outstanding balance of \$250 under the line of credit at December 31, 2002 and 2003 and March 31, 2004. An officer of the Company personally guarantees the \$250 line of credit (Note 10).

During 2002, the Company entered into a \$3,000 line of credit with a second bank. The line bore interest at 1.0% above the bank's prime rate. The line of credit was not drawn upon as of December 31, 2002. In November 2003, the Company replaced the line of credit with a \$6,000 line of credit with the same bank. The line of credit availability is based upon eligible accounts receivable and inventory. The line bears interest at 1.75% above the bank's prime rate (5.75% at December 31, 2003). The line of credit expires on May 5, 2005. As of December 31, 2003 and March 31, 2004, \$2,407 and \$3,717 was outstanding. In addition, as of March 31, 2004, \$550 of the line of credit was used as security for a letter of credit.

Long-term debt consists of the following as of:

	December 31,		March 31,
	2002	2003	2004
Note payable to bank due November 4, 2005, in monthly installments of \$28 plus interest at 1.5% above the prime rate, secured by certain assets of the Company	\$ 971	\$ 614	\$ 522
Capital lease obligations (Note 8)	317	315	497
	<u>1,288</u>	<u>929</u>	<u>1,019</u>
Less current portion of long-term debt	(436)	(462)	(501)
	<u>\$ 852</u>	<u>\$ 467</u>	<u>\$ 518</u>

The agreement related to the \$6,000 line of credit and note payable contains a covenant that requires the Company to maintain a minimum net worth throughout the life of the borrowings. The covenant was modified as a result of the Company deferring certain revenues under SAB 104 (see Note 2). As of March 31, 2004, the Company was not in compliance with this covenant and certain other covenants. In April 2004, the bank waived all such defaults. The Company is in compliance with this modified covenant and all other covenants related to these borrowings and expects to remain in compliance throughout 2004.

Maturities of long-term debt are as follows:

2004	\$462
2005	383
2006	54
2007	30
	<u>—</u>
	<u>\$929</u>

**(7) Stockholders Equity**

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**Preferred Stock.** During the first quarter of 2000, the Company sold 1,853,200 shares of Series A Convertible Preferred Stock (Series A) at \$6.25 per share, raising total proceeds of \$11,077, net of

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ANIMAS CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

offering costs. Each share of Series A is convertible into the Company's common stock at the option of the holder, at a conversion rate of 1.333 shares of common stock for each share of Series A, subject to certain antidilution rights.

In January and February 2001, the Company sold 1,500,000 shares of Series B Convertible Preferred Stock (Series B) at \$10.00 per share, raising total proceeds of \$14,591, net of offering costs. Each share of Series B is convertible into the Company's common stock at the option of the holder, at a conversion rate of 1.333 shares of common stock for each share of Series B, subject to certain antidilution rights.

During the fourth quarter of 2001, the Company sold 1,814,355 shares of Series C Convertible Preferred Stock (Series C) at \$12.50 per share, raising total proceeds of \$22,617, net of offering costs. In addition, from January to June 2002, the Company sold 581,545 shares of Series C at \$12.50 per share, raising total proceeds of \$7,235, net of offering costs. Each share of Series C is convertible into the Company's common stock at the option of the holder, at a conversion rate of 1.333 shares of common stock for each share of Series C, subject to certain antidilution rights.

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

For each Series C Unit closing in 2003, the proceeds were allocated to the Series C and warrants based on the relative values of each instrument. In valuing the warrants issued from January to April, the underlying value of the common stock was based upon the most recent sale of Series C and the fair value of the warrants issued in November was based upon the mid-point of the estimated initial public offering filing range (see Note 15). Accordingly, approximately \$6,795 of the January to April 2003 proceeds was allocated to the Series C and \$5,063 of the proceeds was allocated to the warrants. Similarly, \$2,815 of the November 2003 proceeds was allocated to the Series C and \$2,185 was allocated to the warrants. In addition, in accordance with EITF Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments (EITF No. 00-27), the issuance costs were not offset against the proceeds in calculating the intrinsic value of the conversion option but were considered in the calculation of the amount shown on the consolidated balance sheet. After considering the allocation of the proceeds based on the relative fair values, it was determined that the Series C had a beneficial conversion feature (BCF) in accordance with EITF No. 98-5 and EITF No. 00-27. Accordingly, a BCF adjustment of \$5,063 was recorded with respect to the Series C in the January to April closing. The value of the BCF was recorded in a manner similar to a dividend, and since the Series C has no maturity date and is convertible at the date of issuance, the BCF was charged to the statement of operations. Additionally, the Company recorded a similar deemed dividend during the fourth quarter of 2003, of \$2,815 for the value of the BCF with respect to the Series C sold at the November 2003 closing. The deemed dividend on the November 2003 closing was limited since the value of the BCF is limited to the amount of the proceeds allocated to the Series C.

The Company's Series A, B, and C automatically convert into common stock in the event of an IPO, as defined (see Note 15). The holders of Series A, B, and C are entitled to dividends at a rate of 8% per year, payable when and if declared by the Company's board of directors. In the event of any liquidation, dissolution, or winding up of the Company, holders of Series A, B, and C are entitled to receive preference to any distributions to holders of common stock and an amount per share equal to the original purchase

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

price per share of the applicable series of preferred stock plus an amount equal to the dividends accrued on each such share, whether or not declared.

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

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

**Stock Options.** The Company currently has two stock option plans, the Animas Corporation 1996 Incentive Stock Plan (1996 Plan) and the Animas Corporation 1998 Equity Compensation Plan (1998 Plan). Under the 1996 Plan, options, stock appreciation rights, or other stock awards, as defined, to purchase 400,000 shares of common stock could have been granted for officers, directors, employees, and consultants. The Company granted 397,760 options under the 1996 Plan. As of December 31, 2003, there were 345,227 options outstanding under the 1996 Plan and no additional grants will be made. Under the 1998 Plan, options and restricted stock can be granted up to a maximum of 2,866,667 shares. As of December 31, 2003, there were 633,619 options available for grant under the 1998 Plan. The options under each plan expire ten years from the date of grant and vest over five years. The plans are both administered by a committee of the board of directors that determines the type, price, and other terms of all grants under each plan. Certain options granted to executive officers are subject to an accelerated vesting provision (see Note 8).



## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

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

	Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share
Balance as of January 1, 2001	1,650,660	\$ 0.19-7.50	\$ 3.98
Granted	579,867	6.00-9.38	8.12
Exercised	(8,000)	4.69	4.69
Terminated	(96,000)	4.69-7.50	5.86
	<u>          </u>	<u>          </u>	<u>          </u>
Balance as of December 31, 2001	2,126,527	0.19-9.38	5.03
Granted	580,733	9.38	9.38
Exercised	(9,333)	4.69	4.69
Terminated	(121,067)	4.69-9.38	6.11
	<u>          </u>	<u>          </u>	<u>          </u>
Balance as of December 31, 2002	2,576,860	0.19-9.38	5.91
Granted	342,115	9.38-14.00	11.39
Exercised	(86,100)	0.21-9.38	1.74
Terminated	(218,267)	4.69-9.38	6.44
	<u>          </u>	<u>          </u>	<u>          </u>
Balance as of December 31, 2003	2,614,608	0.19-14.00	6.70
Granted (Note 13)	28,400	14.00	14.00
Exercised	(48,653)	0.19-9.38	1.74
Terminated	(36,037)	4.69-9.38	8.05
	<u>          </u>	<u>          </u>	<u>          </u>
Balance as of March 31, 2004	2,558,318	\$0.75-14.00	\$ 6.86
	<u>          </u>	<u>          </u>	<u>          </u>

In December 2003, the Company granted options to purchase 141,333 shares of common stock at a price equal to the IPO price or if the IPO did not occur within six months of the grant date, at \$9.38 per share. These options are included in the above table with an exercise price of \$14.00 which equals the midpoint of the filing range (Note 13).

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

The following table summarizes information relating to the Company's stock options based upon each exercise price as of December 31, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Options	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
\$0.19-\$0.38	9,667	1.90	\$ 0.19	9,667	\$0.19
\$0.75	93,333	2.80	0.75	93,333	0.75
\$2.25	181,333	3.20	2.25	181,333	2.25
\$3.75-\$4.50	247,227	4.50	4.15	247,227	4.15
\$4.69	751,333	5.70	4.69	570,933	4.69
\$6.00	18,667	7.00	6.00	1,041	6.00
\$6.75	40,000	6.60	6.75	24,000	6.75
\$7.50	251,667	7.10	7.50	104,000	7.50
\$9.38	880,048	8.50	9.38	263,053	9.38
\$14.00 (Note 13)	141,333	10.00	14.00		
	<u>2,614,608</u>	<u>6.66</u>	<u>\$ 6.70</u>	<u>1,494,587</u>	<u>\$5.09</u>

The following table summarizes information relating to the Company's stock options based upon each exercise price at March 31, 2004:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Options	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
\$0.75	66,667	1.88	\$ 0.75	66,667	\$0.75
\$2.25	181,336	2.25	2.25	181,333	2.25
\$3.75-\$4.50	240,560	3.15	4.13	240,560	4.13
\$4.69	740,080	4.13	4.69	610,880	4.69
\$6.00	18,667	5.10	6.00	1,041	6.00
\$6.75	40,000	4.80	6.75	24,000	6.75
\$7.50	243,533	5.25	7.50	116,067	7.50
\$9.38	857,742	6.15	9.38	310,061	9.38
\$14.00 (Note 13)	169,733	7.35	14.00		
	<u>2,558,318</u>	<u>4.88</u>	<u>\$ 6.86</u>	<u>1,550,609</u>	<u>\$5.33</u>

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The weighted average fair value of the options granted during the years ended December 31, 2001, 2002, and 2003 were \$1.76, \$1.88, and \$1.69, respectively. The weighted average fair value was \$3.65 as of

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## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
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March 31, 2004. The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used are as follows:

	Years Ended December 31,			Three Months Ended March 31,
	2001	2002	2003	2004
Risk-free interest rate	4.95%	4.31%	2.97%	3.09%
Expected life (in years)	5	5	5	5
Dividend yield				
Expected volatility	0%	0%	0%	0 and 70%

For the years ended December 31, 2001, 2002, and 2003, the Company granted a total of 39,988, 14,667, and 1,248 stock options, respectively, to certain consultants. These options were granted with 10-year lives and immediate vesting. The Company has accounted for those options in accordance with EITF 96-18, Accounting for Equity Instruments with Variable Terms That Are Issued for Consideration Other than Employee Services. Under SFAS No. 148, accordingly, the Company recorded non-cash charges of \$178, \$31, and \$50 for the years ended December 31, 2001, 2002, and 2003, respectively. The Company determined the fair value of each option using the Black-Scholes option-pricing model utilizing the same assumptions above except for expected volatility in which the Company assumed 50%, 50% and 80%, for 2001, 2002, and 2003, respectively.

Since the Company's inception, the Company has granted to its employees options to purchase common stock at exercise prices equal to or exceeding the selling price of preferred stock. Accordingly, through September 30, 2003, no compensation expense was recorded in connection with options granted to employees. In the fourth quarter of 2003, the Company granted 35,333 options to purchase common stock at the market price of the stock the date the options were issued. The Company recorded deferred compensation of \$165 based upon the midpoint of the estimated IPO filing range. In addition, in 2002 and 2003, the Company extended the option exercise period of terminated employees as part of a severance arrangement. The Company recorded a compensation charge of \$159 and \$501 in 2002 and 2003, respectively, which represents the difference between the fair value of the common stock and the exercise price on the date the option exercise period was extended. The fair value of the common stock was equal to the Company's fair value of preferred stock.

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

Type	Dates of Expiration	December 31, 2003		March 31, 2004	
		Number of Warrants	Exercise Price Range	Number of Warrants	Exercise Price Range
Series C	January 2013 to November 2013	1,223,762	\$12.50	1,211,998	\$12.50
Common	September 2005 to November 2013	310,727	\$0.19 - \$9.38	269,500	\$0.19 - \$9.38

In the event of an IPO, as defined, 1,206,998 of Series C warrants are automatically cashless exercised and converted into common stock at a conversion rate of 1.333 shares of common stock for each share of Series C. (see Note 13) The remaining 5,000 Series C warrants convert into warrants to purchase 6,666 shares of common stock. Of the common stock warrants, warrants to purchase 116,478 shares of

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
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common stock at a weighted average exercise price of \$4.72 per share will terminate at the closing of the IPO, unless earlier exercised.

**(8) Commitments and Contingencies**

**Licensing Agreement.** In December 1996, the Company entered into an exclusive licensing agreement (Licensing Agreement) with a university to acquire the proprietary rights to manufacture and distribute products developed from certain university patents. The Licensing Agreement is renewable annually through the expiration of the last university patent relating to implantable sensors.

Royalties are payable by the Company to the university based on the net selling price of products developed from the licensed technology. In addition, the Company agreed to pay to the university a portion of any proceeds received from sublicensing the university's patent rights. As part of the Licensing Agreement, the Company must make minimum royalty payments to the university. The annual minimum payment amount of \$50 has been charged to cost of products sold in 2001, 2002, and 2003. There have been no sales of products under this license, and no sublicensing fees have ever been paid by the Company under this license.

**Leases.** In April 2004, the Company began moving its administrative offices and manufacturing and distribution facilities from Frazer, Pennsylvania to West Chester, Pennsylvania. The new operating lease has a ten-year term with two five-year renewal options. As of December 31, 2003, the Company had a \$550 letter of credit for a security deposit in relation to the lease.

The Company has also entered into various capital leases to acquire equipment. The capital leases have remaining terms of 2 to 59 months. The implicit lease interest rates range from approximately 10% to 25%. At December 31, 2002 and 2003, assets acquired under capital leases at a cost of \$1,169 and \$1,290, less accumulated amortization of \$696 and \$915, respectively, are included in property and equipment in the accompanying consolidated balance sheets.

Future minimum payments under the operating and capital leases as of December 31, 2003, as adjusted for the amendment to the lease as noted above, are as follows:

	<u>Operating</u>	<u>Capital</u>
		(Note 6)
2004	\$ 1,068	\$ 164
2005	1,141	121
2006	1,169	66
2007	1,195	33
2008	1,226	
Subsequent to 2008	6,937	
	<u>          </u>	<u>          </u>
Total minimum lease payments	\$12,736	384
	<u>          </u>	<u>          </u>
Less amount representing interest		(69)
		<u>          </u>
Present value of minimum capital lease payments		\$ 315
Less current portion		(129)
		<u>          </u>
		\$ 186
		<u>          </u>

ANIMAS CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
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Rent expense was \$630, \$630 and \$669 for the years ended December 31, 2001, 2002, and 2003, respectively.

**Purchase Agreements.** In August 2003, the Company entered into a three year agreement with one of its suppliers. Minimum commitments under this agreement are \$1,558, \$1,558, and \$1,038 for 2004, 2005 and 2006, respectively.

**Employment and Change in Control Agreements.** In February 2004, the Company entered into an amended employment agreement with its President and Chief Executive Officer, which has an initial term that expires on January 1, 2005. The agreement will continue for successive one-year periods unless either party provides notice to terminate. If a change of control of the Company occurs prior to January 1, 2005, the earliest the agreement will terminate is the second anniversary of the change of control. The agreement provides in the event of certain terminations, as defined, all unvested stock options, restricted stock, or other awards will fully vest. Further, in the event of a change of control, vesting on 24 months of unvested shares will accelerate.

Effective upon the closing of the Company's initial public offering, the Company will enter into an employment agreement with its Chief Financial Officer which will expire December 31, 2006. The agreement provides for an annual salary of \$220 plus incentives. In the event of termination 12 months of unvested stock options will immediately fully vest.

In February 2004, the Company's board of directors approved the Company to enter into agreements with each of its executive officers other than the President and Chief Executive Officer that contain provisions that will be triggered in the event of a change of control and will become effective as of the closing of the IPO. Upon a change of control, such executive officers will receive accelerated vesting on 24-months of their then-unvested shares. In the event that such an executive officer's employment with the Company is terminated for certain reasons during the period commencing 30 days before or one-year after the date of a change of control, such executive officer will receive a lump sum payment equal to one year of his or her then-current base salary. In addition, in the event that such an executive officer has remained employed from the consummation of a change of control through the one-year anniversary of such change of control, such executive officer will receive a lump sum payment equal to one year of his or her then-current base salary. These agreements terminate if a change of control does not occur on or before December 31, 2006.

**401(k) Plan.** The Company maintains a 401(k) Plan for our employees. Employee contributions are voluntary. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. No matching contributions have been made by the Company.

**(9) Income Taxes**

As of December 31, 2003, the Company had approximately \$63,858 of net operating loss carryforwards for federal income tax purposes. These carryforwards expire between 2012 and 2023, if not utilized. In addition, the Company had state net operating loss carryforwards of approximately \$34,390 in Pennsylvania. The state net operating losses are subject to a \$2,000 annual limitation and expire between 2007 and 2023. At December 31, 2003, the Company has approximately \$743 of federal research and development tax credit carryforwards, which expire between 2012 and 2023. In addition, the Company has \$133 in Pennsylvania research and development tax credit carryforwards, which expire between 2017 and 2023.

Under the Tax Reform Act of 1986, the utilization of the Company's net operating loss carryforwards may be limited following a greater-than-50% change in ownership within a three-year period. Due to equity

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

transactions entered into by the Company, a portion of the net operating loss carryforwards may be subject to an annual limitation.

The components of the net deferred tax assets as of December 31:

	2002	2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 21,283	\$ 23,978
Tax credit carryforwards	556	831
Warranty reserve	728	704
Property and equipment, principally due to differences in depreciation	(64)	132
Deferred revenue		1,686
Other	485	796
	<u>22,988</u>	<u>28,127</u>
Total deferred tax assets	22,988	28,127
Less valuation allowance	(22,988)	(28,127)
	<u>          </u>	<u>          </u>
Net deferred tax asset	\$	\$

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance at December 31, 2002 and 2003. The valuation allowance in 2002 and 2003 increased by \$7,920 and \$5,139, respectively, related primarily to additional net operating losses and capitalized research and development costs incurred by the Company.

**(10) Related Party Transactions**

One of the Company's directors is the majority owner of an insurance broker. The Company paid the insurance broker commissions of \$140, \$84, and \$232 in 2001, 2002, and 2003, respectively, for the sale of insurance to the Company.

On February 14, 2001, the Company satisfied a \$1,000 loan from a director in consideration of the issuance to him of 100,000 shares of Series B Preferred Stock.

One of the Company's directors is a partner in the law firm that represented the Company in a lawsuit initiated against a former employee in 2003. The Company incurred fees of \$23 in 2003.

**(11) Supplemental Disclosures of Cash Flow Information**

For the years ended December 31, 2001, 2002, and 2003, and for the three months ended March 31, 2003 and 2004 the Company paid interest of \$67, \$83, and \$215, respectively, and \$38 and \$105, respectively and the Company also incurred \$183, \$190, and \$122, respectively and \$39 and \$219, respectively of capital lease obligations. These have been considered non-cash transactions in the accompanying statement of cash flows.

## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

**(12) Business Segments**

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

**(13) Unaudited Pro Forma Net Loss Per Common Share**

Upon the assumed closing of the Company's IPO, all outstanding shares of the Company's preferred stock will automatically convert into shares of common stock at a conversion rate of 1.333. The following pro forma basic and diluted net loss per share has been computed to give effect to this conversion (using the as converted method) for the year ended December 31, 2003 and the three months ended March 31, 2004. The pro forma basic and diluted net loss per share also gives effect to the issuance of 452,624 shares of Series C Preferred Stock (and related conversion into common stock) with an IPO price of \$15.00 per share pursuant to the automatic cashless exercise of warrants, in accordance with their terms, to purchase 1,206,998 shares of Series C Preferred Stock of an exercise price of \$12.50 per share which will automatically convert into shares of common stock effective upon the assumed closing of the Company's IPO. The warrants may be exercised by paying the exercise price in cash or if they are not exercised prior to the IPO, they will automatically cashless exercise pursuant to a cashless exercise feature based on the IPO. If all of the warrants are exercised for cash, the Company will issue an aggregate of 1,206,998 shares of Series C. Such Series C shares would automatically convert into 1,609,331 shares of common stock.

	Year Ended December 31, 2003	Three Months Ended March 31, 2004
Pro forma net loss per common share, basic and diluted:		
Net loss attributable to common stockholders	\$ (25,682)	\$ (8,084)
Weighted-average shares used in computing net loss per common share, basic and diluted	3,869,844	3,904,769
Adjustments to reflect the effect of the assumed conversion of preferred stock from the date of issuance	8,673,669	9,471,031
Adjustment for cashless exercise of warrants	345,666	603,499
Weighted-average shares used in computing pro forma net loss per common share, basic and diluted	12,889,179	13,979,299
Pro forma net loss attributable to common stockholders per common share, basic and diluted:	\$ (1.99)	\$ (0.58)

Options granted in December 2003 and during the three months ended March 31, 2004 to purchase 169,733 shares of common stock at a price equal to the IPO price or if the IPO price did not occur within six months of the grant date, at \$9.38 per share, will have an exercise price of \$15.00, the Company's IPO price per common share.



## ANIMAS CORPORATION AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Information as of March 31, 2003 and 2004 and the three-month periods then ended is unaudited)  
(in thousands, except share data)

**(14) Unaudited Quarterly Financial Information**

	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(2)	\$ 4,837(2)
Gross margin(1)	907	1,526	2,803	5,457	3,751	4,502	6,689	1,786	1,750
Loss before deemed dividend	(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)
Weighted average shares basic and diluted	3,857,778	3,859,316	3,863,360	3,865,983	3,867,431	3,870,168	3,870,716	3,871,079	3,904,769

(1)Gross margin is calculated by subtracting Cost of Products Sold from Net Revenues in the Statements of Operations.

(2)See Note 2 regarding deferred revenue.

**(15) Planned Initial Public Offering**

On February 10, 2004, the Board of Directors, subject to stockholder approval, approved a stock split of the Company's common stock on a four-for-three basis, on or prior to the effectiveness of the Company's registration statement in connection with its IPO. On May 7, 2004, the Company filed an amendment to its certificate of incorporation implementing the stock split. All common share, options, warrants and per share amounts in the accompanying financial statements have been retroactively adjusted to reflect the stock split for all periods presented.

If the IPO is consummated under the terms anticipated, the following also would occur on or before the closing of the IPO.

the increase in the authorized number of shares of common stock to 100 million, and the authorization of 10 million shares of undesignated preferred stock.

the issuance of shares of Series C pursuant to a cashless exercise or cash exercise of warrants to purchase shares of Series C.

the conversion of all of the Company's outstanding preferred stock (including shares of Series C issued related to the exercise of warrants discussed above).

the exercise of warrants, which otherwise expire upon the closing of this offering, to purchase shares of common stock.

the conversion of warrants to purchase 5,000 shares of Series C into warrants to purchase common stock.

the implementation of the Company's 2004 Equity Incentive Plan and 2004 Stock Purchase Plan.

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**4,250,000 Shares**

**ANIMAS CORPORATION**

**Common Stock**

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**PROSPECTUS**

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Through and including June 13, 2004 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**Piper Jaffray**

**Thomas Weisel Partners LLC**

**JPMorgan**

**May 19, 2004**