

ANIMAS CORP  
Form 10-Q  
August 09, 2004

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D. C. 20549**

**FORM 10-Q**

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

For the quarterly period ended June 30, 2004

or

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

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

**ANIMAS CORPORATION**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**23-2860912**  
(I.R.S. Employer  
Identification No.)

**200 LAWRENCE DRIVE, WEST CHESTER, PA**  
(Address of principal executive offices)

**19380**  
(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

Yes  No .

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes  No .

Common stock outstanding at July 30, 2004: 19,206,426 shares

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**ANIMAS CORPORATION AND SUBSIDIARIES  
FORM 10-Q**

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SIGNATURES

- CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)  
CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)  
CERTIFICATION PURSUANT TO SECTION 906
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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements****ANIMAS CORPORATION AND SUBSIDIARIES****Consolidated Balance Sheets  
(unaudited)**

	<b>June 30, 2004</b>	<b>December 31, 2003</b>
	<b>(in thousands except share data)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 55,749	\$ 384
Accounts receivable, net of allowance for doubtful accounts of \$1,447 in 2004 and \$1,285 in 2003	17,319	13,178
Inventories	5,228	3,335
Cost associated with deferred revenue	1,264	1,025
Prepaid expenses and other current assets	978	575
	<hr/>	<hr/>
Total current assets	80,538	18,497
Property and equipment, net	5,272	3,899
Deposits and other assets	103	297
Restricted cash		550
	<hr/>	<hr/>
Total assets	<b>\$ 85,913</b>	<b>\$ 23,243</b>
	<hr/>	<hr/>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Line of credit	\$ 507	\$ 2,657
Current portion of long-term debt	5,389	462
Accounts payable	3,846	2,752
Accrued expenses	5,973	3,283
Deferred revenue	15,715	5,179
	<hr/>	<hr/>
Total current liabilities	15,715	14,333
Other liabilities	1,080	1,140
Long-term debt	428	467
	<hr/>	<hr/>
Total liabilities	<b>17,223</b>	<b>15,940</b>
	<hr/>	<hr/>

Commitments and contingencies

Stockholders' equity:

Series A, B, and C Preferred stock, \$0.01 par value; authorized 8,353,200 shares; none issued and outstanding in 2004 and 7,097,724 in 2003		71
Common stock, \$0.01 par value; authorized 100,000,000 shares in 2004 and 24,000,000 shares in 2003; issued and outstanding 19,192,560 shares in 2004 and 3,987,282 in 2003	193	40
Additional paid-in capital	157,319	90,544
Deferred compensation	(200)	(178)
Accumulated deficit	(88,622)	(83,174)
	<u>        </u>	<u>        </u>
Total stockholders' equity	<u>68,690</u>	<u>7,303</u>
Total liabilities and stockholders' equity	<u>\$ 85,913</u>	<u>\$ 23,243</u>

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

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**Table of Contents****ANIMAS CORPORATION AND SUBSIDIARIES****Consolidated Statements of Operations  
(unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
	<b>(in thousands except share and per share data)</b>			
Net revenues	\$ 20,420	\$ 9,205	\$ 25,257	\$ 16,585
Operating expenses:				
Cost of products sold	7,446	4,703	10,533	8,332
Research and development expenses	1,347	1,216	2,672	2,488
Selling, general and administrative expenses	8,907	7,947	17,312	14,860
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total operating expenses	17,700	13,866	30,517	25,680
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Income (loss) from operations	2,720	(4,661)	(5,260)	(9,095)
Interest income	53	14	54	15
Interest expense	(137)	(57)	(242)	(94)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Net income (loss)	\$ 2,636	\$ (4,704)	\$ (5,448)	\$ (9,174)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Deemed dividend - beneficial conversion feature of preferred stock		(152)		(5,063)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Net income (loss) attributable to common stockholders per share	\$ 2,636	\$ (4,856)	\$ (5,448)	\$ (14,237)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Basic net income (loss) attributable to common stockholders per share	\$ 0.24	\$ (1.25)	\$ (0.72)	\$ (3.68)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Diluted net income (loss) attributable to common stockholders per share	\$ 0.14	\$ (1.25)	\$ (0.72)	\$ (3.68)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Weighted average shares - basic	11,037,815	3,870,168	7,530,011	3,868,775
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

Weighted average shares - diluted	<u>18,291,612</u>	<u>3,870,168</u>	<u>7,530,011</u>	<u>3,868,775</u>
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The accompanying notes are an integral part of the consolidated financial statements.

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**Table of Contents****ANIMAS CORPORATION AND SUBSIDIARIES**

**Consolidated Statements of Stockholders Equity**  
**Six Months Ended June 30, 2004**  
**(unaudited)**

	<u>Preferred stock</u>		<u>Common stock</u>		<u>Additional paid-in capital</u>	<u>Deferred compensation</u>	<u>Accumulated deficit</u>	<u>Total stockholders equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
<b>(in thousands except share and per share data)</b>								
Balance, December 31, 2003	7,097,724	\$ 71	3,987,282	\$ 40	\$ 90,544	\$ (178)	\$(83,174)	\$ 7,303
Sale of common stock at \$15.00 per share, net of offering costs of \$2,390			4,887,500	49	65,741			65,790
Exercise of stock warrants to purchase preferred stock	55,084	1			406			407
Exercise of stock options and warrants to purchase common stock			152,463	2	582			584
Deferred compensation			5,333		76	(76)		
Cashless exchange of warrants			637,378	6	(6)			
Amortization of deferred compensation						54		54
Conversion to common stock	(7,152,808)	(72)	9,522,604	96	(24)			
Net loss							(5,448)	(5,448)
	<u>                    </u>	<u>          </u>	<u>                    </u>	<u>          </u>	<u>                    </u>	<u>          </u>	<u>                    </u>	<u>                    </u>
Balance, June 30, 2004		\$	19,192,560	\$ 193	\$ 157,319	\$ (200)	\$(88,622)	\$ 68,690
	<u>                    </u>	<u>          </u>	<u>                    </u>	<u>          </u>	<u>                    </u>	<u>          </u>	<u>                    </u>	<u>                    </u>

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



Table of Contents**ANIMAS CORPORATION AND SUBSIDIARIES****Consolidated Statements of Cash Flows  
(unaudited)**

	<b>Six Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(in thousands)</b>	
Cash flows from operating activities:		
Net loss	\$ (5,448)	\$(14,237)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,055	745
Non-cash compensation and interest expense	54	484
Bad debt expense	442	809
Deemed dividend		5,063
Other	12	(8)
Changes in net assets and liabilities:		
Accounts receivable, net	(4,583)	(2,135)
Inventories	(1,893)	337
Prepaid expenses and other current assets	(403)	(239)
Deposits and other assets	194	9
Restricted cash	550	
Cost associated with deferred revenue	(239)	
Accounts payable	2,637	(641)
Accrued expenses and other liabilities	503	1,056
Deferred revenue	794	
	<hr/>	<hr/>
Net cash used in operating activities	(6,325)	(8,757)
	<hr/>	<hr/>
Cash flows from investing activities:		
Purchases of property and equipment	(2,163)	(753)
	<hr/>	<hr/>
Net cash used in investing activities	(2,163)	(753)
	<hr/>	<hr/>
Cash flows from financing activities:		
Proceeds from lines of credit	12,102	1,000
Repayments on lines of credit	(14,759)	(500)
Proceeds from issuance of common stock	66,374	23
Repayments on long-term debt	(271)	(245)
Proceeds from sale of preferred stock	407	11,731
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Net cash provided by financing activities	<u>63,853</u>	<u>12,009</u>
Net increase in cash and cash equivalents	55,365	2,499
Cash and cash equivalents at beginning of period	<u>384</u>	<u>1,134</u>
Cash and cash equivalents at end of period	<u>\$ 55,749</u>	<u>\$ 3,633</u>

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

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**ANIMAS CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands, except share data)**  
**(unaudited)**

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

Animas Corporation (the Company) manufactures and distributes insulin pumps as well as ancillary pump supplies required for the use of the pump. The Company, a Delaware corporation founded in 1996, is located in West Chester, Pennsylvania. It received clearance from the Food and Drug Administration (the FDA) for its first insulin pump in February 2000 and began shipping this product in July 2000. The Company received clearance for its third-generation pump, the IR 1200, in October 2003 and began shipping it in April 2004. In 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.

In May 2004, the Company completed its initial public offering (IPO) in which it sold of 4,887,500 shares of its common stock at \$15 per share. Net proceeds to the Company were approximately \$65.8 million. As of the closing date of the offering, all of the convertible preferred stock outstanding was converted into 9,522,604 shares of common stock.

As of June 30, 2004, the Company had cash and cash equivalents of \$55.7 million. The Company expects to have negative cash flows from operations for most of 2004. The Company expects increased selling and administrative expenses relating to the promotion of the IR 1200 as well as increased spending for personnel and infrastructure improvement. The Company believes that its current cash, lines of credit, and cash generated from operations, will be sufficient to meet anticipated cash needs for working capital and capital expenditures into 2005 and the foreseeable future.

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

**Unaudited Interim Results.** The accompanying financial statements for the three and six months ended June 30, 2004 and 2003 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 and six months ended June 30, 2004 and 2003 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 and six months ended June 30, 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 subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

**Cash and Cash Equivalents.** The Company considers all highly liquid debt instruments with an original maturity of three months or less when purchased to be a cash equivalent.

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

Accounts receivable are net of allowances for doubtful accounts of \$1,447 and \$1,285 at June 30, 2004 and December 31, 2003, respectively. Bad debt expense was \$234 and \$442 for the three and six months ended June 30, 2004 and \$224 and \$809 for the three and six months ended June 30, 2003, respectively. The related write-offs of accounts receivable were \$191, \$280, \$58 and \$58 for these periods, respectively.

**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

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the claims. Such costs are recorded at the time of shipment. At June 30, 2004 and December 31, 2003, accrued product warranties totaled \$1,737 and \$1,734, respectively, and are classified as a current liability in accrued expenses (\$660 and \$608, respectively) and are classified as a long-term liability in other liabilities (\$1,077 and \$1,126, respectively) in the accompanying consolidated balance sheets. A tabular reconciliation of the changes in the Company's product warranty liability is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Balance at beginning of period	\$ 1,743	\$ 1,410	\$ 1,734	\$ 1,775
Warranty expense	209	340	805	164
Warranty claims settled	(215)	(221)	(802)	(410)
	\$ 1,737	\$ 1,529	\$ 1,737	\$ 1,529

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 Income (Loss).** Comprehensive income (loss) represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. No separate statement of comprehensive income (loss) has been presented because comprehensive income (loss) was equal to net income (loss) in the three and six months ended June 30, 2004 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. The Company defers revenues associated with training until it has been delivered.

During the six months ended June 30, 2004, approximately 82% 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. During the period of November 1, 2003 to March 31, 2004, the Company initiated an upgrade program in which the Company offered to each new patient purchasing an IR 1000 pump the option to upgrade to the IR 1200 pump at no additional charge. As required by SAB 104, the Company deferred the recognition of net revenues on all pump shipments with an upgrade obligation. As of June 30, 2004, the Company had deferred revenues associated with the pump upgrade program of approximately \$5.5 million and related costs associated with deferred revenue of approximately \$1.3 million. This deferred 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 estimated 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 during the third quarter of 2004. As a result of this program, the Company's net revenues for the second quarter of 2004 were and we expect the third quarter 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 the third quarter will cause a corresponding postponement of net revenues to future periods.

Revenues from products sold directly to domestic and international distributors are recognized upon shipment, and are approximately 18% of Company net revenues during the six months ended June 30, 2004. Distributors have no right of return. The Company has no post-shipment obligations to its distributors.

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**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 three and six months ended June 30, 2004 and 2003, based on the fair value method, at the grant date under SFAS No. 148, the Company's net income (loss) and net income (loss) per share would have been reported as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income (loss) attributable to stockholders, as reported	\$ 2,636	\$ (4,856)	\$ (5,448)	\$ (14,237)
Add Non-cash employee compensation as reported	8	438	16	464
Deduct Total stock-based employee compensation expense determined under fair value-based method for pro forma net loss	(154)	(94)	(279)	(191)
Pro forma net income (loss) attributable to common stockholders	<u>\$ 2,490</u>	<u>\$ (4,512)</u>	<u>\$ (5,711)</u>	<u>\$ (13,964)</u>
Income (loss) attributable to common stockholders per share:				
Basic, as reported	<u>\$ 0.24</u>	<u>\$ (1.25)</u>	<u>\$ (0.72)</u>	<u>\$ (3.68)</u>
Basic, pro forma	<u>\$ 0.23</u>	<u>\$ (1.17)</u>	<u>\$ (0.76)</u>	<u>\$ (3.61)</u>
Diluted, as reported	\$ 0.14	\$ (1.25)	\$ (0.72)	\$ (3.68)

	_____	_____	_____	_____
Diluted, pro forma	\$ 0.14	\$ (1.17)	\$ (0.76)	\$ (3.61)
	_____	_____	_____	_____

*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.

### (3) Inventories

Inventories consist of the following as of:

	<u>June 30, 2004</u>	<u>December 31, 2003</u>
Raw Material	\$ 1,598	\$ 1,064
Work in process	2,165	423
Finished goods	1,465	1,848
	_____	_____
	\$5,228	\$ 3,335
	_____	_____

### (4) Business Segment

A single management team reporting to the President and Chief Executive Officer comprehensively manages the business operations of the Company. The Company does not operate separate lines of business or separate business entities with respect to any of its products. In addition, the Company does not conduct any operations outside the United States. The Company does not prepare discrete financial statements with respect to separate product areas. Accordingly, the Company does not have separately reportable segments as defined by SFAS No. 131,

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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.

**(5) Income (Loss) per Share**

The table below sets forth the reconciliation of the numerators and the denominators of the Company's basic and diluted income (loss) per share computations for the three and six months ended June 30, 2004 and 2003.

	Three Months Ended June 30,			Six Months Ended June 30,		
	Net Income (Loss)	Shares	Per Share Amount	Net Income (Loss)	Shares	Per Share Amount
<b>2004</b>						
Basic	\$ 2,636	11,037,815	\$ 0.24	\$ (5,448)	7,530,011	\$ (0.72)
Dilutive effect of:						
Stock options		1,643,542				
Warrants		482,699				
Preferred stock		5,127,556				
	<hr/>	<hr/>		<hr/>	<hr/>	
Diluted	\$ 2,636	18,291,612	\$ 0.14	\$ (5,448)	7,530,011	\$ (0.72)
<b>2003</b>						
Basic	\$(4,856)	3,870,168	\$ (1.25)	\$(14,237)	3,868,775	\$ (3.68)
Dilutive effect of:						
Stock options						
Warrants						
Preferred stock						
	<hr/>	<hr/>		<hr/>	<hr/>	
Diluted	\$(4,856)	3,870,168	\$ (1.25)	\$(14,237)	3,868,775	\$ (3.68)

For the six months ended June 30, 2004 and the three and six months ended June 30, 2003, diluted income (loss) per share is identical to basic income (loss) per share as the Company is in a net loss position and the common equivalent shares are considered anti-dilutive. For the three months ended June 30, 2004, 2,334 common stock options were excluded from the diluted calculation because the effect would be anti-dilutive. For the six months ended June 30, 2004, 2,565,105 common stock options and 153,027 common warrants were excluded from the diluted calculation because the effect would be anti-dilutive.

**(6) Quarterly Financial Information****Quarterly Results**

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	2002				2003				2004	
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr
Net revenues	\$ 3,639	\$ 4,929	\$ 6,851	\$ 8,179	\$ 7,380	\$ 9,205	\$ 11,291	\$ 6,244	\$ 4,837	\$ 20,420
Gross margin	907	1,526	2,803	5,457	3,751	4,502	6,689	1,786	1,750	12,974
Net income (loss)	(5,413)	(5,587)	(4,964)	(3,410)	(4,470)	(4,704)	(2,212)	(6,418)	(8,084)	2,636
Deemed dividend					(4,911)	(152)		(2,815)		
Net income (loss) attributable to common stockholders	<u>\$ (5,413)</u>	<u>\$ (5,587)</u>	<u>\$ (4,964)</u>	<u>\$ (3,410)</u>	<u>\$ (9,381)</u>	<u>\$ (4,856)</u>	<u>\$ (2,212)</u>	<u>\$ (9,233)</u>	<u>\$ (8,084)</u>	<u>\$ 2,636</u>
Basic net income (loss) attributable to common stockholders per share	<u>\$ (1.40)</u>	<u>\$ (1.45)</u>	<u>\$ (1.28)</u>	<u>\$ (0.88)</u>	<u>\$ (2.43)</u>	<u>\$ (1.25)</u>	<u>\$ (0.57)</u>	<u>\$ (2.39)</u>	<u>\$ (2.01)*</u>	<u>\$ 0.24</u>
Diluted net income (loss) attributable to common stockholders per share	<u>\$ (1.40)</u>	<u>\$ (1.45)</u>	<u>\$ (1.28)</u>	<u>\$ (0.88)</u>	<u>\$ (2.43)</u>	<u>\$ (1.25)</u>	<u>\$ (0.57)</u>	<u>\$ (2.39)</u>	<u>\$ (2.01)*</u>	<u>\$ 0.14</u>

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

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**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**CAUTIONARY STATEMENT PURSUANT TO SAFE HARBOR PROVISIONS OF THE PRIVATE SECURITIES LITIGATION ACT OF 1995:**

*This report and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. When used in this report and the documents incorporated herein by reference, the words anticipate, believe, estimate, may, expect, intend, and similar expressions are generally intended to identify forward-looking statements. These forward-looking statements include, among others, the statements in Management's Discussion and Analysis of Financial Condition and Results of Operations about our:*

*estimate of the length of time that our existing cash, cash equivalents and marketable securities, expected revenue, and interest income will be adequate to finance our operating and capital requirements;*

*expected losses;*

*expectations for future capital requirements;*

*expectations for increases in operating expenses;*

*expectations for increases in research and development, and marketing, general and administrative expenses in order to develop products, manufacture commercial quantities of reagents and products, and commercialize our technology;*

*expectations for the development of an improved insulin pump;*

*expectations for generating revenue; and*

*expectations regarding new or expanded collaborations and for the performance of our existing collaboration partners regarding the development and commercialization of products incorporating our technologies.*

*Our actual results could differ materially from the results expressed in, or implied by, these forward-looking statements. Potential risks and uncertainties that could affect our actual results include the following:*

*technical issues or the failure of the IR 1200 to gain significant market acceptance;*

*failure to capture recurring purchases of ancillary supplies by patients using our pumps;*

*any significant disruption with vendors;*

*any failure to maintain profitability;*

*the failure of our ezSet Infusion Set to be fully-developed or commercially accepted;*

*technological breakthroughs in diabetes monitoring, treatment, or prevention that could render our products obsolete;*

*failure to comply with any FDA or foreign regulations;*

*an inability to attract and retain personnel;*

*competition;*

*an inability to adequately protect our intellectual property;*

*product liability lawsuits;*

*the failure to secure or retain third party coverage or reduced reimbursement for our products by third party payors; and,*

*general economic conditions.*

*These and other risks and uncertainties that could affect our actual results are discussed in this report and in our other filings with the Securities and Exchange Commission, particularly the section entitled Risk Factors in our Registration Statement on Form S-1 which went effective on May 19, 2004. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements other than as required by applicable law.*

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

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### **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.

Our approximately 50-person direct sales force promotes our pump in the United States to healthcare professionals and patients. In addition, our approximately 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 the six months ended June 30, 2004, approximately 82% of our 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.** During the period November 1, 2003 to March 31, 2004 (the *Period*), we implemented a program that allowed patients in the United States, at their option and at no additional cost, to upgrade their IR 1000 pump purchased during the *Period* to the IR 1200 insulin pump when it became 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. 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 during the third quarter of 2004. We do not anticipate the need for additional product upgrade programs in the foreseeable future.

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 do 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 were subject to this upgrade program. We also deferred the associated cost of products sold on shipments of pumps under the upgrade program. Net revenues are 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 estimated 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 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 during the third quarter of 2004. As a result of this program, our net revenues for the second quarter of 2004 were and we expect the third quarter of 2004 to be increased by the recognition of net revenues deferred from previous quarters, as we ship upgraded pumps or patients decline the upgrade. A delay of our obligations under this upgrade program in the third quarter would cause a corresponding postponement of net revenues to future periods.

**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.

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**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 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.

During the six months ended June 30, 2004, approximately 82% of our products were sold directly to patients. We bill these patients directly or bill their healthcare payors. Levels of reimbursements from third party payors vary depending upon the specific benefits provided under each patient's coverage. At the time of sale, we record revenues net of third party contractual allowances, which represent the difference between the established selling price and third party payor payments.

Consistent with SAB 104, 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

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portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of our operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for our products, competitive conditions, product development efforts, approvals of regulatory agencies, and product cost. If actual results differ from these projections, or if our expectations of future results change, it may be necessary to adjust the valuation allowance. As a result of the historic losses, the Company has provided a full valuation allowance for the deferred tax assets.

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

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**Table of Contents****Three Months Ended June 30, 2004 and 2003**

**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 June 30,**

	<b>2004</b>		<b>2003</b>		<b>Change, 2004/2003</b>	
	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
<b>(in thousands)</b>						
<b>Consolidated Statements of Operations</b>						
Net revenues	\$20,420	100.0%	\$ 9,205	100.0%	\$11,215	121.8%
Operating expenses:						
Cost of products sold	7,446	36.5	4,703	51.1	2,743	58.3
Research and development expenses	1,347	6.6	1,216	13.2	131	10.8
Selling, general and administrative expenses	8,907	43.6	7,947	86.3	960	12.1
Total operating expenses	17,700	86.7	13,866	150.6	3,834	27.7
Income (loss) from operations	2,720	13.3	(4,661)	(50.6)	7,381	158.4
Interest income	53	0.3	14	0.1	39	278.6
Interest expense	(137)	(0.7)	(57)	(0.6)	(80)	140.4
Net income (loss)	2,636	12.9	(4,704)	(51.1)	7,340	156.0
Deemed dividend			(152)	(1.7)	152	100.0
Net income (loss) attributable to common stockholders	\$ 2,636	12.9%	\$ (4,856)	(52.8)%	\$ 7,492	NM
<b>Net Revenues, Cost of Products Sold and Gross Margin</b>						
<b>Net Revenues</b>						
Insulin pumps	\$15,798	77.4%	\$ 5,946	64.6%	\$ 9,852	165.7%
Ancillary supplies	4,622	22.6	3,259	35.4	1,363	41.8
Total	\$20,420	100.0%	\$ 9,205	100.0%	\$11,215	121.8%
<b>Cost of Products Sold</b>						
Insulin pumps	\$ 4,750	63.8%	\$ 2,510	53.4%	\$ 2,240	89.2%
Ancillary supplies	2,696	36.2	2,193	46.6	503	22.9

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Total	\$ 7,446	100.0%	\$ 4,703	100.0%	\$ 2,743	58.3%
<b>Gross Margin</b>						
Insulin pumps	\$ 11,048	85.2%	\$ 3,436	76.3%	\$ 7,612	221.5%
Ancillary supplies	1,926	14.8	1,066	23.7	860	80.7
Total	\$ 12,974	100.0%	\$ 4,502	100.0%	\$ 8,472	188.2%

**Gross Margin %**

Insulin pumps	69.9%	57.8%
Ancillary supplies	41.7%	32.7%
Total	63.5%	48.9%

**Net Revenues.** In the three months ended June 30, 2004, net revenues increased by \$11.2 million, or 121.8%, to \$20.4 million from \$9.2 million from the comparable period in 2003. The increase in net revenues was a result of the shipment of the \$2.3 million of unfulfilled orders for the IR 1200 pump from the first quarter of 2004, the recognition of \$3.7 million of revenue deferred from prior periods under the pump upgrade program, \$3.8 million in increased demand primarily for the IR 1200 and \$1.4 million in increased shipments of ancillary supplies. Net revenues from domestic and foreign sales were \$19.5 million and \$0.9 million, respectively, in the three months ended June 30, 2004 and \$8.7 million and \$0.5 million, respectively, in the comparable period in 2003. Our average selling price of pumps remained relatively stable over this period.

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Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges, and other ancillary supplies increased by \$1.4 million, or 41.8%, in the three months ended June 30, 2004 versus the same period in 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 from sales of ancillary supplies reflected our growth in the number of patients using our pumps in the comparable three month periods 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 during the third quarter of 2004. As a result, our net revenues in the 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. As of June 30, 2004 we had deferred revenues associated with the pump upgrade program of approximately \$5.5 million.

**Cost of Products Sold.** Cost of products sold increased \$2.7 million or 58.3%, to \$7.4 million in the three months ended June 30, 2004 from \$4.7 million in the comparable period of 2003. This increase reflected the increase in net revenues in the three months ended June 30, 2004 from the comparable period of 2003. However, as a percentage of net revenues, cost of products sold decreased to 36.5% in 2004 from 51.1% in 2003. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies for supplies and pump materials, better manufacturing yields of our pumps, and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by \$2.2 million, or 89.2% in the three months ended June 30, 2004 as compared to the comparable period of 2003. Costs associated with the additional pumps shipped under the pump upgrade program and the unfulfilled orders shipped from the first quarter were \$1.7 million in the quarter.

**Gross Margin.** Gross margin increased to 63.5% in the three months ended June 30, 2004 from 48.9% in the comparable period of 2003. Gross margin for pumps increased to 69.9% in 2004 due to increases in sales volume, better absorption of overhead, improved yields, and lower cost of raw materials. The pump upgrade program and the shipment in the second quarter of the unfulfilled orders from the first quarter contributed to the improvement of the gross margin through the better absorption of overhead. The effect of the shipment of pumps under the pump upgrade program and the unfulfilled orders contributed 3.7% to the improvement of the gross margin for pumps. Ancillary supplies gross margin increased to 41.7% in the three months ended June 30, 2004 from 32.7% 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 for the third quarter will remain consistent with the second quarter of 2004 as the results for the third quarter will continue to benefit from the additional units produced as part of the pump upgrade program during the prior quarter. Gross margin will then decline slightly for the fourth quarter due to the fulfillment of all pumps associated with the pump upgrade program. Additionally, it is anticipated that the combination of the expected increase in net revenues from sales of ancillary supplies, 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 \$131,000, or 10.8%, to \$1.3 million for the three months ended June 30, 2004 from \$1.2 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 decreased to 6.6% for the three months ended June 30, 2004 from 13.2% in the comparable period of 2003. The percentage decrease in research and development expenses resulted primarily from the growth of our net revenues. In future quarters, we expect research and development expenditures as a percentage of net revenues to decline due to 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 \$960,000, or 12.1%, to \$8.9 million in the three months ended June 30, 2004 from \$7.9 million in the comparable period of 2003. Of this increase, \$544,000 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 \$97,000 and professional fees of \$56,000 contributed to higher SG&A costs in the three months ended June 30, 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 the anticipated growth of our 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.

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***Interest Expense.*** Interest expense increased to \$137,000 in the three months ended June 30, 2004 from \$57,000 in the comparable period of 2003. This reflects a higher outstanding debt balance than in the prior year quarter. The increase in average debt was primarily the result of higher borrowing under our credit lines for the period. These costs should decline in future periods as the proceeds raised in the initial public offering in May 2004 were used to paydown the lines of credit in June 2004.

***Deemed Dividend Beneficial Conversion Feature of Preferred Stock*** In connection with issuances of preferred stock in the three months ended June 30, 2003, we recorded a non-cash charge of \$152,000 that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock. There was no similar item in the three months ended June 30, 2004.

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**Table of Contents****Six Months Ended June 30, 2004 and 2003**

**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.

**Six Months Ended June 30,**

	<b>2004</b>		<b>2003</b>		<b>Change, 2004/2003</b>	
	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
<b>(in thousands)</b>						
<b>Consolidated Statements of Operations</b>						
Net revenues	\$25,257	100.0%	\$ 16,585	100.0%	\$8,672	52.3%
Operating expenses:						
Cost of products sold	10,533	41.7	8,332	50.2	2,201	26.4
Research and development expenses	2,672	10.6	2,488	15.0	184	7.4
Selling, general and administrative expenses	17,312	68.5	14,860	89.6	2,452	16.5
Total operating expenses	30,517	120.8	25,680	154.8	4,837	18.8
Loss from operations	(5,260)	(20.8)	(9,095)	(54.8)	3,835	42.2
Interest income	54	0.2	15	0.1	39	260.0
Interest expense	(242)	(1.0)	(94)	(0.6)	(148)	(157.4)
Net loss	(5,448)	(21.6)	(9,174)	(55.3)	3,726	40.6
Deemed dividend			(5,063)	(30.5)	5,063	100.0
Net loss attributable to common stockholders	\$ (5,448)	(21.6)%	\$ (14,237)	(85.8)%	\$8,789	61.7%
<b>Net Revenues, Cost of Products Sold and Gross Margin</b>						
<b>Net Revenues</b>						
Insulin pumps	\$ 16,969	67.2%	10,908	65.8%	6,061	55.6%
Ancillary supplies	8,288	32.8	5,677	34.2	2,611	46.0
Total	\$25,257	100.0%	16,585	100.0%	8,672	52.3%
<b>Cost of Products Sold</b>						
Insulin pumps	\$ 5,735	54.4%	4,367	52.4%	1,368	31.3%

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Ancillary supplies	4,798	45.6	3,965	47.6	833	21.0
Total	\$10,533	100.0%	8,332	100.0%	2,201	26.4%
<b>Gross Margin</b>						
Insulin pumps	\$11,234	76.3%	6,541	79.3%	4,693	71.7%
Ancillary supplies	3,490	23.7	1,712	20.7	1,778	103.9
Total	\$14,724	100.0%	8,253	100.0%	6,471	78.4%

**Gross Margin %**

Insulin pumps	66.2%	60.0%
Ancillary supplies	42.1%	30.2%
Total	58.3%	49.8%

**Net Revenues.** In the six months ended June 30, 2004, net revenues increased by \$8.7 million, or 52.3%, to \$25.3 million from \$16.6 million from the comparable period in 2003. The increase in net revenues was a result of the recognition of \$3.7 of revenue deferred during the year ended December 31, 2003 associated with the pump upgrade program, increased demand for the IR 1200 and increased shipments of ancillary supplies caused by the increases in customer base on a comparative basis. Net revenues from domestic and foreign sales were \$23.5 million and \$1.8 million, respectively, in the six months ended June 30, 2004 and \$15.4 million and \$1.2 million, respectively, in the comparable period in 2003. Pump net revenues increased by \$6.1 million due to an increase in unit shipments. Our average selling price of pumps remained relatively stable over this period.



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Net revenues from ancillary supplies, consisting of infusion sets, pump cartridges, and other ancillary supplies increased by 46.0% in the six months ended June 30, 2004 versus the comparable period of 2003. The increase was due to increased unit sales, while prices remained near prior period levels. The growth also reflected our growth in the number of patients using our pumps in the comparable six month period of 2004 and 2003 and our retention of patients from prior years.

**Cost of Products Sold.** Cost of products sold increased by \$2.2 million or 26.4%, to \$10.5 million in the six months ended June 30, 2004 from \$8.3 million in the comparable period of 2003 reflecting the increase in net revenues in the six months ended June 30, 2004 from the comparable period of 2003. However, as a percentage of net revenues, cost of products sold decreased to 41.7% in 2004 from 50.2% in 2003. Primary factors that contributed to the decrease included better absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies for supplies and pump materials, better manufacturing yields of our pumps, and improvement in labor and manufacturing efficiency. Cost of insulin pumps sold increased by \$1.4 million, or 31.3% in the six months ended June 30, 2004 as compared to the comparable period of 2003. The rate of this increase was lower than the rate of increase of pump sales due to the economies and efficiencies described above. Costs associated with the additional pumps shipped under the pump upgrade program and the unfulfilled orders shipped from the first quarter were \$1.7 million in the six month period.

**Gross Margin.** Gross margin increased to 58.3% in the six months ended June 30, 2004 from 49.8% in the comparable period of 2003. Gross margin for pumps increased to 66.2% in 2004 due to increases in sales volume, better absorption of overhead, improved yields and lower cost of raw materials. The pump upgrade program and the shipment of the unfulfilled orders from the first quarter contributed to the improvement of the gross margin through the better absorption of overhead. The effect of the shipment of pumps under the pump upgrade program and the unfulfilled orders contributed 3.7% to the improvement of the gross margin for pumps. Ancillary supplies gross margin increased to 42.1% in the six months ended June 30, 2004 from 30.2% in the comparable period of 2003. Gross margin improvement for ancillary supplies was due to lower cost sources of supply.

**Research and Development.** Research and development expenses increased \$184,000, or 7.4%, to \$2.7 million for the six months ended June 30, 2004 from \$2.5 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 decreased to 10.6% for the six months ended June 30, 2004 from 15.0% in the comparable period of 2003. The percentage decrease in research and development expenses resulted primarily from the growth in our net revenues. In future periods, we expect research and development expenditures as a percentage of net revenues to decline due to the growth of our net revenues.

**Selling General and Administrative Expenses.** SG&A expenses increased by \$2.5 million, or 16.5%, to \$17.3 million in the six months ended June 30, 2004 from \$14.9 million in the comparable period of 2003. Of this increase, \$1.2 million was primarily related to higher costs principally associated with increased headcount in the sales, clinical, and marketing functions supporting increased selling activity for existing pumps and ancillary supplies, as well as the launch of the IR 1200. In addition, higher administrative personnel costs of \$237,000 and professional fees of \$80,000 contributed to higher SG&A costs in the six months ended June 30, 2004.

**Interest Expense.** Interest expense increased to \$242,000 in the six months ended June 30, 2004 from \$94,000 in the comparable period of 2003. This reflects a higher outstanding debt balance than in the comparable period. The increase in average debt was primarily the result of higher borrowing under our credit lines. These costs should decline in future periods as the proceeds raised in the initial public offering in May 2004 were used to paydown the lines of credit in June 2004.

***Deemed Dividend Beneficial Conversion Feature of Preferred Stock.*** In connection with issuances of preferred stock in the six months ended June 30, 2003, we recorded a non-cash charge of \$5.1 million that represented the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock. There was no similar item in the six months ended June 30, 2004.

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**Table of Contents****Seasonality and Quarterly Results**

Our business is affected by the reimbursement practices of third party payors. Many patients defer purchasing discretionary durable medical equipment, such as our insulin pumps, until they have satisfied their insurance deductibles which typically occur in the latter half of the calendar year. As a result, despite our annual growth in net revenues, our net revenues in the first quarter of 2003 were lower than the fourth quarter of 2002.

**Quarterly Results**

	2002				2003				2004	
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd 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	\$ 20,420
Gross margin	907	1,526	2,803	5,457	3,751	4,502	6,689	1,786	1,750	12,974
Net income (loss)	(5,413)	(5,587)	(4,964)	(3,410)	(4,470)	(4,704)	(2,212)	(6,418)	(8,084)	2,636
Deemed dividend					(4,911)	(152)		(2,815)		
Net income (loss) attributable to common stockholders	\$ (5,413)	\$ (5,587)	\$ (4,964)	\$ (3,410)	\$ (9,381)	\$ (4,856)	\$ (2,212)	\$ (9,233)	\$ (8,084)	\$ 2,636
Basic net income (loss) attributable to common stockholders per share	\$ (1.40)	\$ (1.45)	\$ (1.28)	\$ (0.88)	\$ (2.43)	\$ (1.25)	\$ (0.57)	\$ (2.39)	\$ (2.01)*	\$ 0.24
Diluted net income (loss) attributable to common stockholders per share	\$ (1.40)	\$ (1.45)	\$ (1.28)	\$ (0.88)	\$ (2.43)	\$ (1.25)	\$ (0.57)	\$ (2.39)	\$ (2.01)*	\$ 0.14

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

Net revenues increased from \$7.4 million in the first quarter of 2003 to \$11.3 million in the third quarter of 2003. In the fourth quarter of 2003 and the first quarter of 2004, our net revenues decreased due to our deferral of \$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, in the first quarter of 2004, were impacted by our decision to stop shipment of pumps for the last three weeks in March 2004 in anticipation of the launch of the IR 1200 in April 2004. Revenue for the second quarter of 2004 benefited from the shipment of \$2.3 million in revenue delayed at the end of the first quarter and an additional \$3.7 million of deferred revenue as a result of the pump upgrade program.

Gross margin improved from 50.8% in the first quarter of 2003 to 59.2% in the third quarter of 2003. The gross margin for the fourth quarter of 2003 and the first quarter of 2004 dropped to 28.6% and 36.2%, respectively, due to the deferral of net revenues and associated costs due to the upgrade program and the decision to stop shipments of pumps for the last three weeks of March 2004. The gross margin in the second quarter of 2004 increased to 63.5% as a result of the increased absorption of overhead due to the increased volume of pumps from the pump upgrade program, the shipment in the second quarter of the unfulfilled orders from the first quarter and the increased demand and improvements in the cost of the ancillary supplies.

Net loss before deemed dividend declined from \$9.4 million in the first quarter of 2003 to \$2.2 million in the third quarter of 2003. Net loss increased in the fourth quarter of 2003 and the first quarter of 2004 to \$6.4 million and \$8.1 million, respectively, due to the pump upgrade program and the resulting deferral of net revenues and associated costs. Additionally, the net loss was increased due to our decision to stop the shipment of pumps for the last three weeks of March 2004. In the second quarter of 2004, net income increased to \$2.6 million. This was the result of additional revenue associated with the shipment of additional pumps due to the pump upgrade program, the shipment in the second quarter of the unfulfilled orders from the first quarter and the increased demand.

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

### **Liquidity and Capital Resources**

Historically, we have funded our operations primarily through the sale of equity securities yielding net proceeds of \$79.9 million through the quarter ended March 31, 2004. On May 25, 2004, we closed our IPO of 4,250,000 shares of our common stock at \$15 per share. Additionally, the underwriters exercised the over-allotment option for the purchase of 637,500 additional shares of our common stock at the offering price of \$15. Net proceeds, including the exercise of the over-allotment option, were approximately \$65.8 million.

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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 no amounts were outstanding at June 30, 2004. We also have an equipment lease financing loan of \$429,000 outstanding at June 30, 2004.

**Cash Used in Operating Activities.** Cash used in operating activities was \$6.3 million and \$8.8 million in the six months ended June 30, 2004 and 2003, respectively. The major use of cash was to fund the losses of \$5.4 million and \$14.2 million for the six months ended June 30, 2004 and 2003, respectively. Our accounts receivable increased by \$4.6 million and \$2.1 million during the six months ended June 30, 2004 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 offset by increases in accounts payable and accrued expense and other liabilities.

During 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 shipped the IR 1200 replacement pumps during the second quarter of 2004, we did not generate any additional cash due to these upgrade shipments. We anticipate the same to occur in the third quarter of 2004. As a result, in 2004, we believe 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 of the purchase of approximately \$2.2 million and \$753,000 of capital expenditures for the six months ended June 30, 2004 and 2003, respectively. The capital expenditures were primarily for manufacturing equipment and computer equipment to support the significant growth in our business during that period and to position us for expected growth in 2004 and beyond.

**Cash Provided by Financing Activities.** Net cash provided by financing activities was \$63.9 million and \$12.0 million for the six months ended June 30, 2004 and 2003, respectively. The net cash provided by financing activities during the six months ended June 30, 2004 was primarily due to our IPO which raised net proceeds of \$65.8 million. These amounts were partially offset by the repayment of debt. The net cash provided by financing activities during the six months ended June 30, 2003 was primarily due to proceeds of \$11.7 million from the sale of preferred stock.

**Bank Credit Facilities.** We have a line of credit with a bank under which we can borrow a maximum of \$6.0 million at an interest rate of 1.75% above the bank's prime rate. This line of credit contains a debt covenant that requires that we maintain a certain net worth throughout the term of this line of credit. 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 June 30, 2004, there was no amount outstanding on this line of credit. 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 June 30, 2004, there was no amount outstanding on this line 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 June 30, 2004, the principal amount outstanding was \$429,000.

**Operating Leases.** At June 30, 2004, commitments related to future lease payments under operating leases, including the lease for our new facility, are \$565,000 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 June 30, 2004. At June 30, 2004, we had \$550,000 outstanding on a letter of credit for a security deposit on the lease for our new facility.

As of June 30, 2004, we had cash and cash equivalents of \$55.7 million. 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 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. 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.

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**Item 3. 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 June 30, 2004, we had no amounts outstanding under our credit facilities.

Although approximately 4% and 7% of our net revenues for the three and six months ended June 30, 2004, respectively 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 June 30, 2004, we were not engaged in any foreign currency hedging activities.

**Item 4. Controls and Procedures**

- (a) **Evaluation of disclosure controls and procedures.** Our chief executive officer and chief financial officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were designed and functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.
- (b) **Changes in internal controls.** There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control over financial reporting that occurred during the fiscal quarter ended June 30, 2004 which materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities**

- (a) None.
- (b) None.
- (c) Set forth below is information regarding shares of common stock and preferred stock that we issued during the fiscal quarter ended June 30, 2004. Also included is the consideration, if any, received by us for those shares, and information relating to the section of the Securities Act of 1933, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.
  - i. Preferred Stock Issuances

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1. During May of 2004, warrants to purchase 43,320 shares of our Series C Preferred Stock were exercised at an exercise price of \$9.38 per share. In addition, warrants to purchase 5,000 shares of our Series C Preferred Stock were converted at the closing of our IPO into warrants to purchase 6,666 shares of our common stock. Warrants to purchase 587,254 shares of our Series C Preferred Stock were exercised by cashless exercise immediately prior to the closing of our IPO resulting in the issuance of an aggregate of 630,574 shares of our Series C Preferred Stock.
2. Upon the closing of our IPO, each outstanding share of our preferred stock converted into 1.333 shares of our common stock.

### ii. Common Stock Issuances

1. In May and June of 2004, our stockholders exercised warrants to acquire 43,561 shares of common stock at a weighted average exercise price of \$4.78 per share
  2. In May of 2004, warrants to purchase 72,914 shares of our common stock were exercised by cashless exercise resulting in the issuance of an aggregate of 50,124 shares of our common stock.
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As used above, the term "cashless exercise" refers to the surrender of a portion of a warrant as payment for the exercise price of the portion of the warrant exercised. No underwriters were involved in the foregoing sales of securities. We issued these securities in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Rule 506 of Regulation D promulgated thereunder relative to sales by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and that they could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of common stock described above included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

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

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

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

Underwriting discounts and commissions	\$5,131,875
Finders' fees	
Expenses paid to or for the Underwriters	
Other expenses	2,390,394
	<hr/>
Total expenses	\$7,522,269
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All of the foregoing expenses were direct or indirect payments to persons other than (i) directors, officers or their associates; (ii) persons owning ten percent (10%) or more of the Company's common stock; or (iii) affiliates of the Company

The net proceeds of the offering, including the exercise of the over-allotment option, to the Company (after deducting the foregoing expenses) were \$65,790,231. From the effective date of the Registration Statement, the net proceeds have been used for the following purposes:

Purchases of real estate  
Acquisition of other businesses

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Repayment of indebtedness	4,767,234
Working capital	6,009,306
Cash equivalents	<u>55,013,691</u>
	<u>\$65,790,231</u>

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

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

(e) None.

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**Item 3. Defaults Upon Senior Securities**

(a) None.

(b) None.

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

No matters were submitted to a vote of security holders during the three months ended June 30, 2004.

**Item 5. Other Information**

None.

**Item 6. Exhibits and Reports on Form 8-K**

(a) Exhibits

(31.1) Certification Pursuant to Rule 13a-14(a)/15d-14(a).

(31.2) Certification Pursuant to Rule 13a-14(a)/15d-14(a).

(32.1) Certification Furnished Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

As of the date of filing of this Form 10-Q, the Company did not file any Current Reports on Form 8-K during or after the second quarter of fiscal 2004. The Company did not furnish any Current Reports on Form 8-K during the second quarter of fiscal 2004 but has furnished the following Current Report on Form 8-K since the second quarter and prior to the filing of this Form 10-Q:

The Company furnished a Current Report on Form 8-K on July 30, 2004, under Item 7 (Financial Statements and Exhibits) and Item 12 (Results of Operations and Financial Condition), announcing that it had issued a press release and held a broadly accessible conference call to discuss its financial results for its fiscal quarter ended June 30, 2004.

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

/s/ Richard Baron

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Richard Baron  
Vice President Finance and Chief Financial Officer

DATE: August 9, 2004

Animas Corporation  
(Registrant)